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A modular approach to diabetes structured education: Effects on patient knowledge, self-efficacy, self-management and patient experience in diabetic kidney disease

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Acknowledgments

This work is dedicated to the memory of Niru Goenka whose inspiration, drive and excitement for diabetes research and education made this project happen.

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Abstract

Background: Diabetic kidney disease (DKD) is a serious chronic complication of diabetes, associated with increased risk of cardiovascular disease, end stage kidney disease and mortality. Intensive management, incorporating dietary and lifestyle changes with pharmacological agents, has been shown to reduce associated risks of DKD. This requires multiple self-management (SM) actions to optimise risk factors including diabetes, hypertension and hyperlipidaemia. Diabetes structured education (DSE) is integral to diabetes management and research shows DSE is beneficial to knowledge, SM activities, and diabetes control (Dekain et al., 2009; Speight et al., 2010). However, little evidence exists in DSE focused on DKD, despite the increased risk of mortality associated with the condition and NICE guidelines (NICE, 2008; NICE, 2003) encouraging education to optimise management of diabetes and kidney disease.

Research aims: To determine whether complication-specific DSE for DKD has an impact on SM, self-efficacy (SE), and knowledge related to DKD, and to identify what effect education has on participants.

Methods: A mixed method approach, combining quantitative questionnaires and semi-structured qualitative interviews was utilised. A standalone education module specifically for adults with DKD was provided for participants, tailored to the needs of this distinct group.

Results: A single education module demonstrated positive changes in SM activities, specifically seeking information, asking questions regarding biomedical results and following suggestions to alter dietary and exercise habits. Improvements were also seen in knowledge related to DKD. Significant positive correlations were demonstrated between

SM and SE outcomes related to seeking support and discussing worries with family and friends. Qualitative results identified that social support can have a negative or positive impact on participants depending on the nature of the support. It was also found that participants felt healthcare professionals did not inform them of their biomedical results.

Conclusion: An education module specifically for DKD allows the information to be tailored to meet the needs of participants to a greater extend, which is in keeping with NICE guidelines (NICE, 2003). A single education session had a positive impact on participants demonstrated by improvements in DKD knowledge, SE and increased engagement in SM activities. Healthcare professionals can improve partnership with patients through the sharing of, and the significance of, biomedical information. This could have a benefit in reducing the health burden of DKD considering its morbidity and mortality risk.

Declaration of original work

I hereby declare that work contained herewith is original and is my own work. Qualitative research described within this work was carried out in conjunction with the Centre for Public Health at Liverpool John Moores University. This work has not been previously submitted in support of a Degree, qualification or other course.

Signed ……..……..……..Date……..

Presentation of work

An abstract containing selected data within this report has been submitted for consideration for presentation at the Diabetes UK Professional Conference 2015 in London 11th-13th March 2015. The outcome of this submission will be known by the end of December 2014. The abstract is entitled **"**Effectiveness of diabetes essentials: kidneys (DEKID), a standalone group education session for diabetic kidney disease on patient self-reported self-management behaviours".

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Abbreviations

ACCORD: Action to Control Cardiovascular Risk in Diabetes

ADVANCE: Action in Diabetes and Vascular disease

BP: Blood Pressure

CKD: Chronic Kidney Disease

CKD-SE: Chronic Kidney Disease Self-Efficacy

CKD-SM: Chronic Kidney Disease Self-Management

COCH: Countess of Chester Hospital NHS Foundation trust

CVD: Cardiovascular disease

DCCT: Diabetes Control and Complications Trial

DKD: Diabetic Kidney Disease

DN: Diabetic Nephropathy

DoH: Department of Health

DSE: Diabetes structured education

HbA1c: Glycated haemoglobin

KiKS: Kidney Knowledge Survey

LTC: Long term condition

NHS: National Health Service

NICE: National Institute of Clinical Excellence

QOF: Quality and Outcomes Framework

SE: Self-efficacy

SM: Self-management

T1DM: Type 1 diabetes

T2DM: Type 2 diabetes mellitus

1. Introduction

1.1 Impact of Diabetes

Diabetes Mellitus (diabetes) is a serious chronic metabolic condition characterised by elevated levels of circulating blood glucose, hyperglycaemia. The two most common variants of diabetes are Type 1 diabetes (T1DM) and Type 2 diabetes (T2DM) which are characterised as a total lack of the pancreatic hormone, insulin, as in T1DM and a relative lack of insulin or ineffective use of insulin by the body as in T2DM. Both conditions result in an inability to maintain normal glycaemic control (World Health Organization (WHO), 2011).

Long term suboptimal management of diabetes results in hyperglycaemia leading to structural damage to cells and alterations to normal metabolic processes. These alterations are associated with development of microvascular and macrovascular complications of diabetes and increased atherosclerosis risk (Fowler, 2008; Williams & Pickup, 1999). The extent of hyperglycaemia is directly associated with an increase in the risk of developing secondary complications, particularly the microvascular complications nephropathy, retinopathy, and neuropathy, affecting the eyes, kidneys and nerves respectively (Stratton et al., 2000).

1.2 Diabetic kidney disease

The umbrella term diabetic kidney disease (DKD) is used to describe CKD in the presence of diabetes whether it is a direct result of diabetes (diabetic nephropathy) or from vascular complications which often accompanies diabetes.

Development of CKD is substantially increased in those with diabetes in comparison to the general population, with an eight and twelve fold increase observed for women and men

with diabetes, respectively (Hippisley-Cox &Coupland, 2010). The prevalence of DKD varies from 18% to 30% across the UK, with variation attributed to ethnicity, age and level of deprivation (Diabetes Kidney Care, 2011). The impact of the condition is impaired kidney function, which can deteriorate to end stage kidney disease (ESKD). DKD is the leading cause of ESKD in the UK, with 21.9% of all cases attributed to the condition (Farrington, Udayaraj, Gilg, & Feehally, 2009).

Research has demonstrated that the risk of developing the detrimental effects of diabetes, such as DN can be reduced with appropriate long term management of diabetes and cardiovascular risk markers (Diabetes Control and Complications Trial [DCCT], 1993).

1.3 Diabetic kidney disease management

The National Institute of Clinical Excellence (NICE) states that approaches to delay or prevent the progression of CKD to end stage kidney failure are warranted (NICE, 2008) and have set out national guidelines in the areas of both diabetes (NICE, 2003) and chronic kidney disease (NICE, 2008) for the appropriate management of the conditions. Intensive treatment targeting hyperglycaemia, dyslipidaemia, hypertension and microalbuminuria has been shown to slow the progression of diabetic kidney disease (Gaede, Vedel, Parving, & Pedersen, 1999). Therefore interventions which aid a reduction in these clinical indicators of risk must be a priority in order to reduce the impact of DN.

Recommendations are set out in both guidelines calling for high quality programmes to educate patients and enable them to make informed decisions about their care in partnership with healthcare professionals (NICE, 2003; NICE, 2008).

1.4 Structured Education: Diabetes & CKD

The National Institute of Clinical Excellence (NICE) recommends that the National Health Service (NHS) provides structured education for all people with diabetes (NICE, 2003). NICE (2003) advise that such education should be adapted to the needs and personal choices of the individual.

There is a wealth of research on the benefits of diabetes structured education (DSE) (Davies, et al., 2008; Deakin, Cade, Williams & Greenwood, 2006; Deakin, McShane, Cade & Williams, 2009), however a clear lack of educational interventions in the earlier stages of CKD has been identified, which may have the benefit of reducing the progression of the condition (Byrne et al., 2011). Current CKD education tends to focused on individuals in the pre-dialysis or dialysis stage (Li et al., 2011; Mason, Khunti, Stone, Farooqi, & Carr, 2008). Moreover, there is a lack of research, which potentially reflects a lack of education, in the area of specific education tailored to the management of DKD, which would combine the education needs of managing two chronic conditions.

Taking this into consideration, the provision of education which combines diabetes and CKD self-management (SM), in the form of modular education specifically for DKD could meet NICE recommendations (NICE, 2003) more thoroughly, tailoring the content and allowing for greater flexibility to meet the needs of this distinct group. The potential exists for this type of tailored education to improve the outcomes of individuals with DKD.

1.5 The Research Proposal

This current study will look at the effects that the education module “Diabetes Essentials: Kidneys” has on knowledge, SE, and SM. It will combine these outcomes with qualitative research findings to gain an understanding about the participant’s experience of education and its impact on their self-care practice. Research into the role of education in the

management of DKD and its impact on individuals with the condition will be examined. The study aims to identify the associations between the complex outcome measurements and explore the effects of education specifically for a population with DN.

2. Literature Review

2.1 Diabetic Kidney Disease

2.1.1 Pathophysiology of Diabetic Kidney Disease

It is accepted that the pathophysiology of DKD in T1DM and T2DM is very similar (Wolf, 2004). CKD is defined as a reduction in glomerular filtration rate (GFR) or kidney damage for three months or longer (Levey et al., 2003). GFR is the best measure of overall kidney function in health and disease (Levey et al., 2003) and estimated GFR (eGFR), calculated using serum creatinine levels is the manner in which GFR should be measured routinely (NICE, 2014).

One of the earliest indications of CKD is damage to blood vessels in the functional cells of the kidneys i.e. the glomerulus capsule, disrupting the normal filtration ability of the kidney (Satchell & Tooke, 2008). During DKD, excess circulating blood glucose combines with proteins forming irregular compounds known as advanced glycosylated end products which are deposited in the glomeruli causing the vascular cell lining to thicken and disrupt normal cellular activity (Sego, 2007). Combined with this, a change in capillary pressure in the glomeruli causes hyperfiltration and hyperperfusion which again leads to thickening of the cell lining (Wolf, 2004). Hypertension and hyperlipidaemia, two common accompanying conditions in diabetes, exacerbate the damage to the vascular cells (Sego, 2007; Hovind, Rossing, Tarnow, Smidt, & Parving, 2001). Other compounds implicated in kidney decline are explained extensively in other literature (Wolf, 2004; Satchell, & Tooke, 2008).

The change in the structural integrity of the glomeruli disrupts its normal functioning and generally results in albumin, a protein which should be retained in the blood during

filtration, passing through the kidneys, in a condition known as microalbuminuria (Satchell& Tooke, 2008). Persistent microalbuminuria is a clinical marker of DKD development, as it is a risk factor for the progression to macroalbuminuria (or proteinuria) which is a characteristic of overt DKD (Hovind, Rossing, Tarnow, Smidt, &Parving, 2001; Satchell& Tooke, 2008). Proteinuria precipitates a fall in the filtration rate of the glomeruli and therefore kidney function decline (Levey et al., 2003). Continued decline in GFR causes progression of DKD with deterioration to end stage kidney disease (ESKD).

Microalbumiuria is not a prerequisite to DKD progression and absence of microalbuminuria is common in older adults with T2DM presenting with other vascular problems (Hill, & Fogarty, 2012). This population present with the glomerular changes, alongside ischemic and vascular changes which results in a fall in GFR in the absence of albuminuria (Hill, & Fogarty, 2012).

Evidence emphasises that progression from microalbuminuria to proteinuria is not an absolute. In T1DM population studies, 58% of microalbuminuria cases returned to normoalbuminuria (Perkins, Ficociello, Silva, Finkelstein, Warram, & Krolewski, 2003) and in a second study, only 30-45% of individuals with microalbuminuria progressed to proteinuria over a ten year period (Gross, de Azevedo, Silveiro, Canani, Caramori, & Zelmanovitz, 2005). This regression or lack of progression was a result of improved management of glycaemia, hypertension and hyperlipidaemia (Gross, de Azevedo, Silveiro, Canani, Caramori, & Zelmanovitz, 2005; Perkins et al., 2003).

The implication of the condition leads to a substantial impact on the individual as well as health services.

2.1.2 Health burden of diabetic kidney disease

DKD is a serious chronic condition with associated complications including hypertension, anaemia, renal bone disease, hyperkalemia, hyperphosphatemia, and ESKD (Diabetes UK, 2013; Levey et al., 2003).

Estimated prevalence of DKD range from 33-45% for those with T1DM (Nathan, 1993; Satchell& Tooke, 2008) and 20-30% for those with T2DM (Nathan, 1993; Department of Health [DoH], 2006). It is the leading cause of ESKD in the UK accounting for 24% of all ESKD diagnoses (Gilg, Castledine & Fogarty, 2012). Of those who require renal replacement therapy (RRT), 14% of cases are due to DKD (Gilg, Castledine & Fogarty, 2012). The progression to the point of RRT is pertinent in view of the increased risk of mortality (Foley et al., 2005).

ESKD has an approximate mortality rates of 15-20% per year for the whole population and results in a mortality rate one hundred times greater among those receiving RRT than the general population (Walker & Buchbinder, 2012). For those with diabetes receiving RRT the mortality rates are substantially higher indicated by an a threefold increase risk those over 85 years of age and a 25 fold increase for those aged 30 to 34 years compared to the general population (Steenkamp, Castledine & Feest, 2012).

A substantial burden of DKD is the association with CVD (Diabetes UK, 2013; Levey et al., 2003). Independently, microalbuminuria is a strong indicator of vascular disease risk (NICE, 2008) while impaired GFR in T1DM is associated with increased risk of coronary artery calcification and in T2DM with increased CVD (de Ferranti et al., 2014).

NHS Kidney Care & NHS Diabetes (2011) identifies CVD as the most common complication of diabetes, however acknowledges DKD as the most severe diabetes complication (Levey et al., 2003). For those with CKD, death from CVD is more likely than

from CKD directly (Levey et al., 2003; Sarnak et al., 2003). One study demonstrated incidence rates of RRT of 3.4 per 100 patient years, compared to death rates of 19.9 per 100 patient years in those with DKD (Foley, Murray, Li, Herzog, McBean, Eggrs & Collins, 2005). In this same study rates of congestive heart failure and myocardial infarction in DKD were 52.3 and 6.9 per 100 patient years respectively, which when compared to rates of RRT, emphasises the higher rates of CVD over RRT in DKD (Foley et al., 2005).

In summary, the increased prevalence of CKD in those with diabetes, the associated significant health burden and increased mortality substantiate the need for appropriate management of affected individuals, and efforts to delay and prevent progression to ESKD.

2.1.3 Quality of Life

Diabetes carries a substantial self-management burden, combining alterations to lifestyle to manage the condition, dealing with short term complications and potentially long term consequences (Polonsky, 2000). Diabetes reduces quality of life (QoL) below that of age matched people without diabetes (0.76 versus 0.80 respectively) (Koopmanschap, 2002). Moreover QoL reduces with the onset of secondary complications of diabetes (0.69) and reduced further with the presence of both a macro- and micro-vascular complication (0.59) (Koopmanschap, 2002).

There is limited research into QoL in patients with CKD, particularly prior to ESKD, and even less so in DKD specifically. The evidence available suggests people with DKD have a lower QoL score than those with CKD without diabetes and this reduces further with increasing duration of DKD (Diabetes Kidney Care, 2011). This reduction is an important consideration of individual management, in combination with the clinical manifestations of the condition.

2.1.4 Cost of diabetic kidney disease

Diabetes is accompanied by a considerable cost implication, with an estimated £23.7 billion or 10% of the total National Health Service (NHS) budget spent on diabetes in the 2010/11 financial year (Hex, Bartlett, Wright, Taylor & Varley, 2012). Direct cost of diabetes incorporates diagnosis and treatment of diabetes and diabetes complications, the latter of which has the most significant financial burden of the disease entity, accounting for 80% of the direct costs (Hex et al., 2012). This financial burden is predicted to rise as a result of the continuing rise in the incidence diabetes and the aging population (Hex et al., 2012).

CKD carries a lesser yet substantial cost burden also, of approximately £1.45 billion in England during 2009/10, which accounted for approximately 1.3% of NHS spending (Hill & Fogarty, 2012). More than half of this spending is implicated in RRT, which is required for only 2% of the CKD population (NICE, 2014).

The number of people in ESKD receiving RRT is growing and propose reasons for this, outlined by Hill & Fogarty (2012) are:

- Increasing prevalence of diabetes which in turn increases rates of CKD and ESKD
- Primary care incentives to identify and manage DKD, leading to increased and earlier management and initiation of treatment
- Increased incidences of ESKD as a result of improved management of cardiovascular risks and reduced mortality as a result
- Greater availability of the service, particularly for those with diabetes, who historically faced greater restrictions in RRT.

Improved service delivery to reduce the cost implication of managing ESKD is advisable (Kerr et al., 2012). Approximately £470 per patient could be saved when appropriate management of hypertention and proteinuria is provided over five years (Kerr et al., 2012). This saving relates to earlier management of CKD in order to reduce progression to ESKD and also reductions in myocardial infarction and stroke risk (Kerr et al., 2012).

It can be concluded that appropriate management of diabetes and its complications are essential in order to improve outcomes, life expectancy, QoL and the associated financial burden.

2.2 Management of diabetic kidney disease

Earlier it was indicate that optimal management of risk factors reduces the risk of DKD, can reverse the earliest indications of the condition and subsequently delays progression of DKD. This is supported by guidelines which encourage early intervention to reduce the health burden of DN (Levey et al., 2003; NICE, 2004; NICE, 2009).

Evidence from the Diabetes Control and Complications Trial (DCCT) shows a reduction in glycated haemoglobin (HbA1c), the clinical marker of diabetes control, to less than 53mmol/mol, through intensive management is associated with an approximate 60% reduction in the risk of development or progression of microvascular complications compared to those with a HbA1c greater than 75 mmol/mol (DCCT, 1993). The DCCT found that intensive diabetes management in T1DM reduces the risk of microalbuminruria and proteinuria by 39% and 54% respectively (DCCT, 1993). The UK Prospective Diabetes Study (UKPDS) of intensive diabetes control in T2DM found that achieving an 11mol/mol (1%) reduction in HbA1c is associated with a 37% risk reduction in microvascular disease including DN (Stratton et al., 2000).

Large multi-centred multi-national randomised control trials have demonstrated that intensive therapy utilizing pharmacological agents and lifestyle education in the management ofHbA1c, hypertension and dyslipidaemia has been shown to be effective in reducing microalbuminuria (The ACCORD Study Group, 2008; DCCT, 1993). The ADVANCE Collaborative Group (2008) demonstrated a significant 86% reduction in DKD development with such intensive interventions.

The Steno-2 study was a multi-factorial approach combining lifestyle and behavioural changes with pharmalogical interventions incorporating optimisation of glycaemia, blood pressure (BP) and dyslipidaemia (Gæde et al., 2003). The study observed a 61% risk reduction in the development or progression of DN when HbA1c was targeted to less than 48mmol/mol, cholesterol to less than 4.5mmol/L, triglycerides to less than 1.7mmol/L and BP to less than 130/80 mmHG (Gæde et al., 2003). This shows the benefits of optimising risk factor control in the management of DKD.

The ACCORD study is notably in this area due to its early termination as a result of increased all-cause mortality (The ACCORD Study Group, 2008). Due to the increase, the intensive glycaemia cohort (targeting HbA1c <42mmol/mol) transitioned to standard treatment (targeting HbA1c 53-63mmol/mol) Although a definitive explanation for this increase has not been established, a number of factors have been proposed, including greater weight gain, higher rates of severe hypoglycaemia, greater levels of anti-hyperglycaemic agents and potentially drug interactions (Ismali-Beigi et al., 2010; Skyler et al., 2009). In terms of the impact on kidney function, there was an unexpected greater reduction in eGFR as a result of intensive diabetes management within the first 24 months (Ismali-Beigi et al., 2010). It is proposed that this decline may have been as a result of improved glycaemia causing an increase in glomerular hyperfiltration which would be represented by a fall in eGFR (Ismail-Beigi et al., 2010). Reduction in GFR does occur in

the early stages of DKD as a result of hyper-function and hypertrophy before stabilising (Mogensen, Christensen, & Vittinghus, 1983).

Despite the differences in eGFR at transition (3.7 years), there was no difference at the end of the study period (5 years) (Ismali-Beigi et al., 2010).This study did identify improvements in micro and macro- albuminuria development which was significantly reduced (21% and 31% respectively) at the end of the intensive treatment phase (3.7 years) (Ismali-Beigi et al., 2010). This reduction was attenuate (15% & 27% respectively) however maintained significance at the end of the 5 year study period (Ismali-Beigi et al., 2010).

No difference in the levels of ESKD was found between intensive and standard care (Ismail-Beigi, et al., 2010). However it is acknowledged that the observation period (5 years) may not have been sufficient for such long term outcomes to become evident. In a longer follow-up period of ten years, the UKPDS study demonstrated cardio- and micro-vascular benefits persisted or increased from interventions to optimise control (Holman, Paul, Bethel, Matthews & Neil, 2008).

The overall consensus is that optimising glycaemic control is important for risk reduction; however it should be considerate of individuals and targets tailored as such (Ismali-Beigi et al., 2010; Skyler et al., 2009). Targeting HbA1c to less than 42 mmol/mol as achieved in the ACCORD study is not warranted and is unsafe practice (Ismali-Beigi et al., 2010).

As mentioned, factors, other than glycaemia, namely hypertension and dyslipidaemia are implicated in the progression to ESKD and are important considerations in the overall management of diabetes, particularly given the associated increased CVD risk (ADVANCE Collaborative Group, 2008; Gæde et al., 2003; Hovind et al., 2001; Ismail-Beigi et al., 2010). Studies support, the prioritising of BP management in DKD in particular (Wolf &

Ritx, 2003; Levey et al., 2013) targeting 130/80 mmHg in order to maximise the protective cardiovascular effect (Wolf & Ritz, 2003; Ruggenenti, Schieppati, & Remuzzi, 2001).

The evidence advocates and NICE guidelines support effective management of risk factors in order to reduce the risk of developing DKD and reduce the progression of ESKD (ADVANCE Collaborative Group, 2008; DCCT, 2003; Gæde, Vedel, Parving, & Pedersen, 1999; NICE, 2008).

2.3 Dietary management in diabetic kidney disease

Lifestyle management is a key factor in DKD. One study showed that the management of risk factors in those with T2DM and microalbuminuria reduces CVD risk, such that treatment of 5 people for 8 years would prevent one CVD event (Gaede et al., 2003).

The Steno-2 study demonstrated improved DKD management utilising pharmacological agents alongside behavioural change strategies and education to control biomedical risk factors (Gæde et al., 1999).

2.3.1 Glycaemic control

The DCCT trial which identified the importance of glycaemic control in reducing the risk of developing diabetes complication, incorporated nutritional behaviours associated with a reduction in HbA1c of 4-11 mmol/mol (Delanhanty & Halford, 1993). This study identified appropriate hypoglycaemia treatment, adjustment of insulin for food intake, limiting additional supper snacks and additional insulin to treat hyperglycaemia as dietary factors aiding improvements of HbA1c in T1DM (Delanhanty & Halford, 1993). This role of the diet in managing diabetes control is supported by the “dose adjustment for normal eating”

(DAFNE) research, which identifies the positive effective matching insulin to carbohydrate amounts, reducing HbA1c by 11.0mmol/mol at six months and 3.6 mmol/mol reduction at 44 months (Speight et al., 2010). This management regime is recommended for those with T1DM and on multiple daily insulin regimes while standardised carbohydrate portions for those with T1DM on fixed insulin regimes is recommended (Dyson et al., 2011). Diabetes UK evidenced based guidelines for the management of T2DM diabetes encourages weight management, physical activity, standardising carbohydrate intake and potentially the use of low glycaemic index foods as beneficial in aiding glycaemic control in T2DM (Dyson et al., 2011).

2.3.2 Hypertension

Hypertension causes an increase in capillary pressure in the glomeruli of the kidneys which causes damage and thickening of the glomerular cell lining which aids the development and progression of DKD (Hovind et al., 2001; Sego, 2007; Wolf, 2004). Lifestyle modification to aid blood pressure control is warranted as a major aspect of HTN management (ADA, 2002). NICE (2011) encourage reductions in excessive alcohol intake, reducing excessive caffeine intakes and offering guidance on healthy eating, exercise and smoking cessation.

Dietary factors other than sodium have been implicated in the optimisation of BP. The Dietary Approaches to Stop Hypertension (DASH) study (1997) identified a significant reduction in BP through dietary measures which combined increased fruits, vegetables and low fat dairy and reduced intake of total fat, saturated fat and cholesterol. The diet therapy followed for an eight week period resulted in a statistically significant BP reduction of 11.6/5.3 mm Hg ($P<0.001$) in individuals with hypertensive (Svetkey, 1999).

The reduction in BP demonstrated in the DASH population is comparable to those with mild HTN requiring monotherapy (Svetkey, 1999). The beneficial effect of this therapy on

BP reduction is increased as baseline BP increases which encouraged dietary interventions, in conjunction with pharamalogical agents in the optimisation of therapy to manage those more hypertensive individuals (Svetkey, 1999).

2.3.3 Dyslipidaemia

Hyperlipidaemia is implicated in the progression of DKD due its effect in exacerbating the damage to the vascular cells (Sego, 2007). Appropriate management of hyperlipidaemia is important in the increased CVD risk in addition to DKD management. The Joint British Societies' (JBS) guidelines suggest targeting treatment to optimise total cholesterol to less than 4.0 mmol/l and LDL cholesterol to less than 2.0 mmol/l or 25% and 30% reduction respectively, whichever has the biggest reduction (Wood, Durrington, & Poulter, 2005).

The Steno study showed beneficial effects in reducing the progression of DKD in T2DM and involved dietary intervention as well as optimisation of medication (Gaede et al., 2003). This study showed statistically significant reduction in total cholesterol, LDL cholesterol and triglycerides (0.6, 0.4 and 0.5 mmol/l respectively) with no significant change in HDL-cholesterol (Gaede et al., 2003). This aim of dietary intervention for this intervention involved targeting total daily intake of fat to less than 30% and saturated fat to less than 10% (Gæde et al., 1999).

Similarity exist with NICE guidelines, which advises those with or at high risk of CVD (which includes those with diabetes) to restrict total fat to 30% or less of total energy intake, saturated fat to 7% or less, dietary cholesterol to less than 300 mg/day and for monounsaturated and polyunsaturated fats to replace saturated fats where possible.

In conclusion, glycaemic control, hypertension, and dyslipidaemia are all areas where dietary and lifestyle behaviour have an impact (NICE, 2004; NICE, 2009; Dyson et al., 2011) and therefore should be encouraged in those with DKD.

2.4 Chronic disease self-management

Long term conditions (LTCs) have become the biggest health burden facing health service provider globally (Barrett 2012). LTCs include diabetes, CKD, CVD, chronic obstructive pulmonary disease and cancers. Not only are incidences of these conditions rising individually, there is also a greater number of people living with more than one chronic disease. Barrett et al., (2012) reports of those with a LTC in Scotland, approximately 40% are living with two LTCs and 23% with two or more conditions.

Each LTC will have individual priorities in terms of lifestyle and dietary management and medication regimes, which lends itself to the proposal that healthcare strategies which incorporate the management of multiple LTCs will improve clinical care (May, Montori & Mair, 2009). Strategies which effectively support people with self-managing their conditions by aiding the combination of LTCs management plans, will aid the burden on individuals, and may lead to greater adherence to medical advice and as result improve the cost effectiveness of health service input (May et al., 2009).

As mentioned earlier the prevalence of CKD increases in those with diabetes, therefore strategies which incorporate the self-management (SM) of both conditions could be beneficial. Research into SM strategies in this area is outlined below.

2.4.1 Diabetes structured education

Structured education for the management of diabetes is considered best clinical practice in order to provide individuals with the empowerment to manage their condition (NICE, 2003). The aim of DSE is to improve knowledge and skills, enable people with diabetes to take control of their condition and to implement SM of the condition into daily living (NICE, 2003).

Numerous studies have reported the benefits of education in the area of diabetes (Deakin, McShane, Cade, & Williams, 2005; Ellis, et al., 2004; Norris, Lau, Smith, Schmid, & Engelgau, 2002) but there is a lack of research focused specifically on the effect of education in the area of development or progression of secondary complications.

A meta-analysis has shown that DSE has a beneficial effect on HbA1c and BP (Deakin, McShane, Cade, & Williams, 2005). Both these outcomes reduce risk of DKD (ADVANCE Collaborative Group, 2008; Ismail-Beigi et al., 2010) and progression to ESKD (Gæde et al., 2003). A limitation of DSE research is the lack of evidence in end point outcomes such as ESKD or mortality, however it is acknowledged that further research is needed in this area (Deakin et al., 2005).

Conflicting evidence exist as to whether DSE, can lead to an improvement in diabetes control measured by HbA1c, which clinically would be the desirable outcome given the relationship between this clinical marker and complications and mortality (DCCT, 1993). Some education studies have shown an improvement in HbA_{1c} (Davies et al., 2008; Deakin, Cade, Williams, & Greenwood, 2006) while others have demonstrated improvements in knowledge, SE and self-management outcomes (Deakin et al., 2005).

Knowledge is a vital factor for education as people require information in order to understand their condition and how their daily lifestyle impacts on its management. Without this knowledge, people have no awareness or reason to change behaviours

(Mason, Khunti, Stone, Farooqi, & Carr, 2008). In theory, people require increased knowledge to improve management of their condition, however improved knowledge through DSE has not been shown to result in improved biomedical outcome measures (Gomersall, Madill, & Summers, 2011; Steed et al., 2005), unless the actual principles of education are implemented and maintained by the individual (Gomersall et al., 2011). This lack of improvement in HbA1c is potentially due to a lack of the new knowledge required to inform the necessary behaviour changes required to effectively manage HbA1c. Also given the progressive nature of diabetes, which is reflected in the need for frequent medical reviews and treatment progression (Koopmanschap, 2002), deterioration in HbA1c can occur when effective strategies for SM are not revised or implemented. This emphasises the need for partnership between health services and patients which is encouraged for diabetes management (NICE, 2003; DoH, 2010).

Educational interventions have found that those who had a greater understanding of the terminology and clinical markers of diabetes and CKD risk factors were those who implemented dietary SM behaviours to a greater degree (Beard, Clark, Hurel, & Cooke, 2010; Goron & Lash, 2011). This suggests that explaining and sharing information regarding clinical markers is beneficial to improved care.

Evidence supports the idea that factors other than knowledge are also implicated in behaviours for diabetes SM (Beard et al., 2010; Knight, Dornan, & Bundy, 2006). DSE will only impact outcomes if behavioural changes are implemented (Knight et al., 2006; Curtin, Walters, Schatell, Pennell, Wise, & Klicko, 2008). Therefore, although knowledge may be a pre-requisite of instigating behavioural change, other factors such as a person's confidence in their capabilities to implement changes or their feeling of self-efficacy (SE) (Sturt, Hearnshaw, & Wakelin, 2010). Also the motivation or willingness they have to change habitual daily living tasks in order to improve SM is of importance (Curtin et al., 2008). However, behavioural changes to optimise diabetes control are acknowledged to

be challenging for individuals to instigate and maintain (Funnell & Anderson, 2004). This is particularly the case when behavioural changes are not considerate of an individual's own priorities, goals, or daily routine (Funnell & Anderson, 2004).

Self-determination is required by the individual in order to implement behavioural changes which itself is a complex process influenced by motivation, knowledge, beliefs, attitude and social support (Al-Khawaldeh, Al-Hassan, & Froelicher, 2012). The ability to instigate the necessary behavioural changes is thought to be related to an individuals' feeling of SE, which is the extent to which a person believes they have the ability to carry out tasks to accomplish goals (Bandura, 1997). Therefore making behavioural changes requires multifaceted actions combining knowledge with the SE to implement SM actions and this is influenced by the personal factors mentioned above. It is proposed that the areas of knowledge, SM skills and SE are all required in order for progress in improving HbA1c (Al-Khawaldeh et al., 2012).

For these reasons, it is understandable that intensive multifactorial interventions incorporating tailored education have been advocated in this area (Gæde et al., 2003).

2.4.2 Chronic kidney disease self-management

Similar to diabetes, it is well accepted that SM is required to manage CKD (Al-Khawaldeh, Al-Hassan, & Froelicher, 2012; Costantini, Beanlands, McCay, Cattran, Hladunewich & Francis, 2008; Li, Wu, Wang, Huang, Yang, Dong, & Liu, 2011; NICE, 2003). For reasons of practicality, logistics and financial burden, the management of CKD cannot be achieved by input solely from health professionals but necessitates the individual's SM on a regular basis for the vast majority of management actions (Costantini, et al., 2008; Curtin, Walters, Schatell, Pennell, Wise, & Klicko, 2008). This involves the ability to change and sustain behaviours in relation to diet, physical activity, medication, self-monitoring and attendance at medical review (Li et al., 2011; Costantini, et al., 2008).

In the area of CKD the provision of education or information is recommended in order for individuals to “fully understand and make informed decisions about their treatment” (NICE, 2008 p15) and should be considerate of what the condition is, how the person can manage their condition and the treatment options (NICE, 2008).

2.4.3 What is effective in education for CKD?

A systematic review of randomised control trials (RCTs) involving educational interventions in CKD (not specifically for DKD) found that a once only group education session supported with written information resulted in short term significant improvements in SE and self-care dialysis knowledge (Mason, Khunti, Stone, Farooqi, & Carr, 2008). This education was specifically targeting people in the pre-dialysis with CKD Stages 4 and 5 who were attending for pre-dialysis care. Positive outcomes were also reported in long term follow-up studies with improvements in knowledge retention, delayed onset of dialysis therapy and greater survival rates at 20 years (Mason et al., 2008).

A systematic review was unable to identify RCT’s of educational intervention in CKD Stages 1 to 3 which were of sufficient quality for inclusion in the review (Mason et al., 2008). An important consideration highlighted by the authors is that the lack of educational interventions in the early stages of CKD may be associated with a high level of late referrals to specialist renal services (Mason et al., 2008). This may be due to a lack of awareness in general practice with regards to deteriorating kidney function and the benefits of referral to a specialist renal team and early intervention. Mason et al., (2008) stipulate that an increase in public awareness of CKD is warranted combined with preventative education. They suggest that ‘a structured intervention aimed at empowering patients with the knowledge, skills, and motivation to help control their blood pressure and

lead healthier lifestyles could help prevent or delay the progression of kidney disease' (Mason et al., 2008, p.949). This was based on a systematic review of interventions which aimed to increase knowledge and motivation, predominantly through individual interactions with pre-dialysis and dialysis patients (Mason et al., 2008). Improvements in a variety of outcomes including SM, reported SE and knowledge at four weeks were reported as well as increased survival (median 2.25 years) at twenty years (Devins, Mendelssohn, Barré, Taub, &Binik, 2005) and delayed onset of 4.6 months for dialysis (Binik et al., 1993).

The long term outcomes trials examined individual educational intervention as opposed to group education sessions however the finding are promising in terms of benefit for those with CKD (Devins et al., 2005). Mason et al., (2008) recognises that there is limited evidence of the use of education intervention in areas of CKD management, with the majority concentrated on the dialysis stage and concordance with dietary and fluid recommendations (Mason et al., 2008)

Mann et al., (2008) supports the use of a small group standalone session to improve outcomes in those in the pre-dialysis stage, suggesting session should be interactive, use problem based learning and be supported with written information (Mann et al., 2005). This has been shown to be effective in improving knowledge, SE and in this population, the willingness to start self-care dialysis (Mann et al., 2005).

2.4.4 Education in diabetic kidney disease

There is a clear lack of evidence in the area of DKD education (Li, Wu, Wang, Huang, Yang, Dong, & Liu, 2011) although studies in diabetes and CKD independently acknowledge the benefits of such an approach in the management of each condition (Deakin et al., 2005; Mason et al., 2008). It is also acknowledge that although diabetes is a major cause of CKD, a distinct lack of research exists in the area of DKD (Li et al., 2011)

and potentially reflects a lack of structured education as routine practice in the area. Studies which incorporate individuals with DKD do not distinguish DKD from CKD or alternatively were not educational only interventions rather were combined with pharmacological therapy (Li et al., 2011).

In a Cochrane systematic review of education programmes specifically for people with DKD (Li et al., 2011), one study examined the effects of education in the early stages of DKD (Steed, Lankester, Barnard, Earle, Hurel, & Newman, 2005). Steed et al., (2005) examined the effects of a DSE program over three months versus routine care in a group of individuals with T2DM and microalbuminuria. Attendance at the education session showed significant improvements in diabetes knowledge, self-reported dietary behaviours, exercise and blood glucose monitoring immediately post intervention (week 5) and additionally at three month follow-up for all these with the exception of dietary behaviours. In respect of dietary behaviours, although these were significantly improved immediately post intervention; by three months this had declined and were no longer significantly different from the control group (Stead et al., 2005). This suggests that, as time from education elapses so too does the implementation of dietary behaviours.

Participation in this course resulted in a 9% attrition rate at the end of the intensive phase (five weeks) and 17% at the three month course end, with a greater number lost in the intervention group (immediate post-intervention 4 participants control group, 9 participants intervention group; at 3-month follow-up 8 participants control group, 12 participants intervention group) (Stead et al., 2005). This has important implications when considering the manner in which education should be delivered, suggesting that greater time commitment results in greater reduction in attendance. This is an important consideration

of current strategies alongside exploration of the reasons for the higher attrition in the intervention group.

Although the study shows that knowledge and SM behaviours are improved by education, this did not correlate with improvement in diabetes management as measured by HbA1c, which showed no difference from the control group at three month follow-up (Stead et al., 2005). This is consistent with other research in the area which indicates that although education positively impacts knowledge and self-reported SM behaviours, this is not reflected in improvements in diabetes control (Al-Khawaldeh et al., 2012; Davies et al., 2008).

As mentioned in a previous section, studies conflict on whether DSE affects HbA1c. The X-pert education did show positive outcomes in HbA1c with DSE, with a statistically significant -5.5mmol/mol difference between the DSE group and control group (Deakin et al., 2006) This is at variance with the current study, however the X-pert study was over fourteen month study duration in comparison to Stead et al. (2005) which investigated a three month period. The measurement of HbA1c involves analysis of the lifespan of erythrocytes, representing 120 days (Rohlfing, Wiedmeyer, Little, England, Tennill, & Goldstein, 2002) therefore potentially studies of shorter duration are less likely to demonstrate a change in HbA1c due to a lack of time for SM changes to affect HbA1c.

2.5 Outcome measures

NICE guidelines on education suggest the relevant outcome measures of DSE are knowledge, motivation and anxiety or depression related to diabetes (NICE, 2003). Education has a positive impact on knowledge, and self-reported SM practices as well as feelings of SE in relation to SM (Deakin et al., 2005; Mason et al., 2008). However the majority of the research does not correlate these behaviour changes to improvements in

HbA1c (Davies et al., 2008; Deakin et al., 2005; Deakin et al., 2006) As stated previously HbA1c is the most popular measurement of successful treatment as it has been directly related to reductions in the risk of complications (DCCT, 1993) and as it is a clinically appropriate standardised measurement which reduces bias. Nonetheless a lack of chance in HbA1c should not result in education being viewed in a negative manner.

As stated previously the progressive and changing nature of diabetes, as well as the multiple factors affecting effective management makes achievement of ideal HbA1c challenging. The challenge of achieving optimal HbA1c (below 58mmol/mol) is reflected in the fact that only 62.2% of the population with diabetes in England & Wales achieved this target (Health and Social Care Information Centre, 2014)

A Cochrane review of DKD education, recognise that instigation and maintenance of behaviours for SM is required to support diabetes control and minimise the progression of DKD (Li et al., 2011). NICE clinical guidelines on the management of diabetes and the provision of education support knowledge development and implementation of SM (NICE, 2003). Studies in diabetes education and in CKD have looked at SM activities, knowledge and levels of SE in order to demonstrate the impact of education on outcomes (Al-Khawaldeh et al., 2012; Curtin et al., 2008; Deakin et al., 2005; Stead et al., 2005). Use of these measures would allow for comparison and includes outcomes identified as important by NICE (2003).

To conclude, education which provides greater personalisation of education to individuals needs aids the management of multiple LTCs. This should be considerate of the needs of specific population sub groups and provide specific disease related knowledge, and effective strategies to improve SE and the necessary skills for SM activities.

2.6 The research questions

2.6.1 Aim of the project

To determine whether a modular approach to diabetes education in the form of complication specific education for DKD has an impact on adults with the condition in terms of SM, SE and knowledge related to DKD and to identify what effect education has on participants.

2.6.2 Research questions

- Does Diabetes Essentials: Kidneys affect self-reported SM activities in relation to DKD?
- What effect does Diabetes Essentials: Kidneys have on self-reported SE?
- What effect does Diabetes Essentials: Kidneys have on knowledge?
- What effect does Diabetes Essentials: Kidneys have on participant experience?

3. Methods

3.1 Study design

This mixed methodology prospective cohort study examined the effects of the structured group education module Diabetes Essentials: Kidneys. The education session aimed to improve knowledge, sense of SE in relation to DKD management and encourage SM practices in relation to DKD to assist people to achieve their goals.

The study took place over a six month period from March to September 2013, incorporating participants attending one of four standalone education modules, which were held monthly. Study participants were followed for a twelve week period. All participants in the research had access to the educational module; therefore no participants had clinical care withheld.

The study provided the opportunity to identify the relationship between the education module and outcome measurements. Quantitative data in the form of self-completed questionnaires for the dependent variables knowledge, SM and SE relating to the educational module were completed immediately prior to the education module and repeated at six and twelve weeks post intervention. Qualitative semi-structured interviews were undertaken six weeks post education intervention in order to determine to a greater and broader degree the effects of the education module on participants. The interviews encouraged participants to provide an insight into their experience of the education module, its effects on their self-care practices and give a greater understanding of the potential relationship which exists between the dependent variables measured.

3.1.1 Ethical approval

Ethical approval for the research project was granted with conditions by National Research Ethic Service (NRES) Committee North West (Preston) on the 26th February 2013. These conditions were met and full approval granted on February 28th 2013 (Appendix 1). The Countess of Chester Hospital NHS Foundation Trust Research and Innovation Department subsequently granted approval for the project (Appendix 2).

3.1.2 Dependent Variable

3.1.2.1 Quantitative data

The Chronic Kidney Disease self- management (CKD-SM) instrument (Lin et al., 2012a);Chronic Kidney Disease self-efficacy (CKD-SE) instrument (Lin et al., 2012b) and the Kidney Knowledge Survey (KiKS)) (Wright, Wallston, Elasy, Ikizler, & Cavanaugh, 2011) were used in this study. These questionnaires did not require licence agreements; however through personal communication with the authors, permission was requested and granted on the basis that the publications were acknowledged (Appendix 7 and Appendix 8).

3.1.2.2 CKD-SM instrument

The CKD-SM instrument (Appendix 11) is a valid and reliable measurement of SM behaviour for individuals with CKD (Lin et al., 2012a). The tool has been used in a population with CKD, mainly stage 2 and stage 3 CKD and has been shown to have good internal consistency and test-retest correlation, and a high sampling adequacy (Lin et al., 2012a).

This questionnaire rates on a scale of one to four, how often the participant completes or considers a certain self-care activity, with one meaning they never carry out the task and four meaning they always carry out the task. The questions investigate the level of SM in relation to factors influencing kidney health including diet, exercise, and smoking, sourcing information, questioning laboratory results and seeking support both from health professionals and social circle. This questionnaire was used at three points during the research, at baseline and six and twelve weeks post intervention.

A major drawback of the CKD-SM instrument for the current research is that there is no English translation of the tool as it was originally developed for use amongst a Taiwanese population. However, a review of the literature failed to identify other suitable CKD specific SM tools and it is acknowledged that there is a lack of validated questionnaires for use in people with CKD (Mason et al., 2008). For that reason the tool was based on the information provided in the English publication of the article in order to produce an English version of the tool. This modification of translating the instrument to English was the only modification made to the tool.

3.2.2.3 CKD-SE instrument

The Chronic Kidney Disease self-efficacy (CKD-SE) instrument (Appendix 12) is used in order to identify the behaviours of individuals with early CKD. It has been shown to have a high sample adequacy and good internal consistency in a population with CKD Stages 1-3 (Lin et al., 2012b). The original instrument was developed in Chinese and translated to English by the instruments' authors. The questionnaire rates on a scale of one to ten how confident the participant feels in relation to a scenario or daily living activity that is important in the management of CKD. A score of one means not

confident in that particular scenario/activity while a score of ten means extremely confident. This questionnaire was used at three points during the research, at baseline, immediately post intervention and six and twelve weeks post intervention.

Unfortunately for both the CKD-SE and CKD-SM instruments there are no published studies which have used the tools as part of an intervention as yet. This is perhaps as they are relatively new tools, therefore there is no available data on the use of the tool to measure change following an intervention. Generic chronic disease and diabetes specific SE (Lorig et al., 1996; Talbot, Nouwen, Gingras, Gosselin, & Audet, 2007) and SM tools are available (Toobert, Hampson & Glasgow, 2000; Wallston, Rothman, & Cherrington, 2007), however it was decided that CKD specific instruments would give a better indication of SM and SE in this population with DKD.

3.1.2.4 KiKS

The KiKS tool (Appendix 13) measured CKD knowledge in patients across all stages of CKD with an emphasis on early CKD (Stages 1- 3). The survey has previously been tested in a group of adults with CKD stages 1-5 and shown to have good internal consistency. Higher scores have been positively and independently associated with younger age, greater health literacy, previous participation in a kidney education class and awareness of CKD diagnosis (Wright et al., 2011).

The survey consists of twenty-eight multiple choice questions. For the purposes of this project, the questionnaire was modified to the extent that questions which addressed issues not included in the education module were removed. This focused participant responses on measuring knowledge based on that which was delivered through the

module being investigated. This eliminated twelve questions and reduced the survey to sixteen multiple choice questions. As the development of the questionnaire weighted all the questions the same, the removal of unsuitable questions did not impact the outcome of the questions used in terms of the validity of the results.

3.1.2.2 Qualitative data

Semi-structured interviews were employed in order to give a greater degree of insight into the participants' experience and views of the education module. The advantage of this type of research is that it gives a greater level of detail and appreciation of human issues and offers more flexibility to identity relationships between complex matters (Bryman & Burgess, 1994; Marshall, 1996). Qualitative research has been described as a method of exploring experiences, perceptions, motivations and behaviour (Clissett, 2008). This is a benefit of this type of research in that themes, opinions or concepts not previously considered by the researchers, and which may be beyond the scope of the quantitative research, can be explored. This methodology allows for participant-led rather than researcher-led outcomes to be identified (Bryman, 2012).

This qualitative research technique followed an interview guide (Appendix 14) which was used to lead the interview. However the semi-structured nature of the interview meant that participant-initiated deviations are encouraged in order to include aspects important to the participant that may not have been considered or investigated by the researcher. All interviews were audio- recorded and transcribed verbatim.

3.2 Population and subjects

3.2.1 Sample and sample size estimation

The current study uses a novel approach to diabetes education due to its disease specific module format. A review of the literature did not identify a similar educational intervention which means no comparable data exist to compute an effect size difference with which to perform a power calculation to determine an appropriate sample size. Consideration of resources and capacity of the group education session was the greatest influential factor of the sample size recruited.

In consideration of time and resources available recruitment to the research study was agreed for all education sessions from March to June 2013. With full capacity this would have resulted in 32 participants (each session has capacity for 8 people, and is delivered once per month). A feasibility study of group structured education in CKD (not specifically a diabetes population) reported 30% recruitment to the study (Byrne, Khunti, Stone, Farooqi, & Carr, 2011). The authors did acknowledge that structured education is a more established aspect of clinical care in the area of diabetes and this would potentially lead to a greater uptake. Indeed published data in SDE reports recruitment of up to 74% (Davies, M. J., et. al., 2008). Using these as guides to potential recruitment figures would suggest ten (30% recruitment) to 24 participants (74% recruitment) in the education sessions would participate in the research.

Bacchetti, Deeks, & McCune, (2011) explain that in a novel study, it is “impossible” to predict whether an intervention will have breakthrough effect, some value or no impact on outcomes. A small sample size would be sufficient to detect breakthrough effects while in a study with no impact a large sample size would be wasteful. A small sample size can be beneficial as it is more cost effective and considerate of time and resources

available (Bacchetti et al., 2011) and potentially assist in further research without creating an unnecessary burden or expense

In the qualitative research, recruitment of subjects used purposive sampling which means those who have knowledge of the topic are involved in the research (Bryman, 2004). Therefore those who participated in the quantitative element of the research were also invited to partake in the qualitative research until study saturation had been achieved.

3.2.2 Recruitment

Suitable participants for this research project were identified from those scheduled to attend the Diabetes Essentials: Kidneys education module delivered at the Countess of Chester Hospital NHS Foundation Trust. Two methods exist for booking a place on this education session. Individuals are either referred onto this module by a healthcare professional, generally a member of the diabetes specialist team, or individuals could contact a dedicated telephone number to reserve a place themselves. (A number of referrals were generated by individuals reserving a place themselves after they had received a letter highlighting their suitability for the module from their GP). Potential participants were contacted by letter to invite them to partake in the research (Appendix 5) and this was subsequently followed up with a telephone call.

3.3.3 Eligibility criteria

3.3.3.1 Inclusion criteria

- Adults over the age of 18 years of age
- Diagnosed diabetes mellitus (type 1 or type 2)
- Diagnosed CKD related to diabetes

- Presenting with either:
    - CKD Stage 3: estimated glomerular filtration rate (eGFR) 30-60 ml/min/1.73m^2
    - Proteinuria: albumin:creatinine ratio (ACR) of 30 mg/mmol or more
- Individuals registered to a GP within Western Cheshire Clinical Commissioning Group (CCG) or under the care of the Diabetes Specialist Team at the Countess of Chester Hospital NHS Foundation Trust

3.3.3.2 Exclusion criteria

- Young persons under the age of eighteen
- Pregnancy
- Unable to provide informed consent
- Unable to communicate proficiently through English
- CKD Stage 4 or 5 (i.e. an eGFR less than 30 mL/min/1.73m^2)
- CKD unrelated to diabetes

3.2.4 Consent

Participants were contacted by postal invitation a minimum of seven days prior to the scheduled first visit and were provided with the participant information (PI) sheet (Appendix 6) at this contact. All participants had the opportunity to talk through the research project with the researcher at the initial telephone contact and again at Visit 1 at the trial site. Written informed consent (Appendix 3) was taken at the first clinic visit prior to any study procedures taking place.

Written consent for those participating in the qualitative component of the research was taken prior to the semi-structured interviews (Appendix 4). For those who opted for this

contact as a telephone interview, their consent form was sent to their home address and returned to the researcher prior to this contact being made.

3.2.5 Participant reimbursement

Through the funding secured for this study from the Cheshire and Merseyside Allied Health Professional (AHP) Research Network participants were reimbursed for their travel and parking expenses incurred during the course of participation in the research.

3.3 Procedures

The delivery of the 'Diabetes Essentials: Kidneys' education module was facilitated by a diabetes specialist nurse (DSN) with specialist interest in DKD and by the author of this research project, who is a registered dietitian. The module is delivered as a standalone session at the Diabetes Unit of the Countess of Chester Hospital (COCH) NHS Foundation Trust. For a description of the education module see Appendix 19. Other study procedures relating to the management and data collection of the quantitative research was carried out by the author.

The qualitative research in the form of the conduct, transcription and analysis of the semi-structured interviews was led by researchers from the Centre of Public Health, Faculty of Health and Social Sciences at Liverpool John Moores University. The study author was involved in the analysis of the interviews in order to provide a second independent interpretation of the key issues, concepts and themes.

The study procedures were carried out over a six month period between March and September 2013, with each participant actively involved for a period of twelve weeks within this time frame. All the study activities were carried out at either the Diabetes Unit at the COCH or in the participants' own home (week 12 self-completed questionnaires).

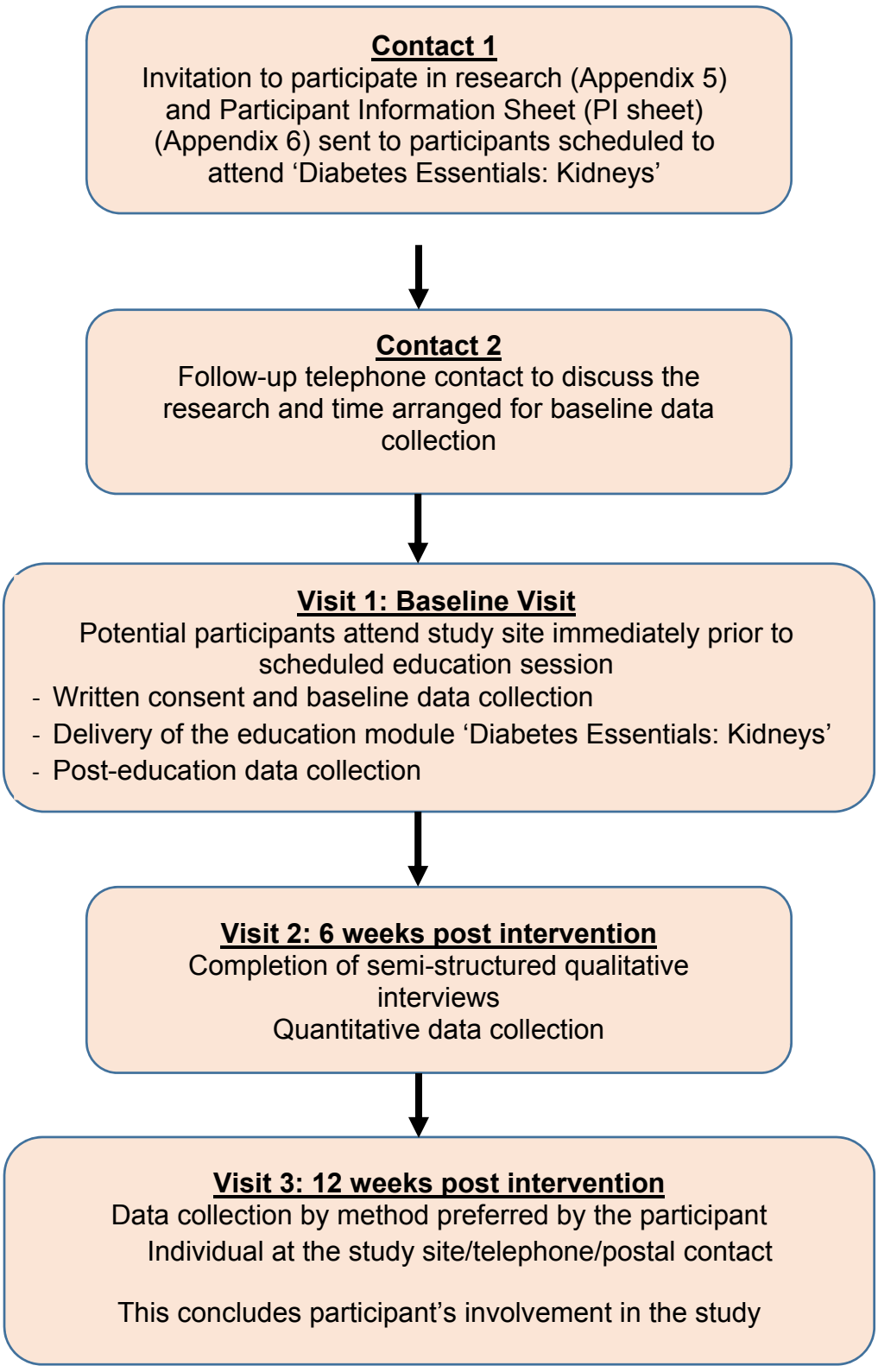

Figure 1: Flowchart indicating participant flow through the study

3.4 Statistical analyses

SPSS statistics 20 (IBM) was used for the statistical analysis of the data. A value of 0.05 was considered statistically significant with a 95% confidence level used to interpret the results.

Each of the demographics was explored using descriptive statistics including the central distributions and dispersion of the data, in order to describe the characteristics of the study population. Sample percentages were calculated for each of the demographics (gender, ethnicity, employment status, educational attainment) and median and inter-quartile rage (IQR) calculated for clinical characteristics (number of other diabetes complications, previous diabetes education, and medication category).

3.4.1 Quantitative data

CKD-SE and CKD-SM questionnaires generated results at three separate time points in the form of ordinal data. Visual inspection of this data using histograms, Q-Q plots and detrended Q-Q plots identified a distribution which was positively skewed. Boxplots of distribution showed the majority of results were skewed towards the higher range of the scales used with whiskers towards the lower values. Median and IQR were used to present the central distribution and dispersion of the results. Friedman tests were used to compare changes in these outcome variables. The KiKS results were in the form of binary data. Percentage correct and in-correct was calculated for this data, which was generated at four distinct time points. Spearman rank-order correlation coefficient was used to detect whether association between CKD-SM, CKD-SE and KiKS existed.

Multivariate logistic regression analyses to estimate relationships between SE, SE and knowledge, however during data analysis it was decided that identifying relationships

between the qualitative and quantitative results would add much more value to the outcomes, above that which would be generated from a regression analysis.

3.4.2 Qualitative data

To fully capture the data all interviews were transcribed verbatim. Each transcript was scrutinised independently by two researchers and an index of all the key issues, concepts and themes devised drawing on issues linked to the aims and objectives of the study combined with issues expressed by participants themselves.

4. Results

4.1 Participant recruitment and progression

All those registered to attend “Diabetes Essentials: Kidneys” between the study period (March to June 2014) were invited to participate in the research, this resulted in invitation to thirty-three patients across four sessions. Twenty-two individuals (66.7%) attended the education session and of those who attended fifteen (68.2%) were recruited to the research.

Of those who agreed to participate, two (13.3%) were excluded from the research due to improvements in biomedical measures (specifically estimated glomerular filtration rate [eGFR]). Thirteen eligible people who meet the inclusion criteria agreed to take part in the research, representing a 39.4% uptake of the research project by those invited. Figure X illustrates participant flow through the study.

Participant attrition for the study was low, with all thirteen of those eligible participants continuing for the duration of the research, completing the three contacts over a three month period. Eleven participated in the qualitative research, as it was felt saturation had been reached in terms of outcomes.

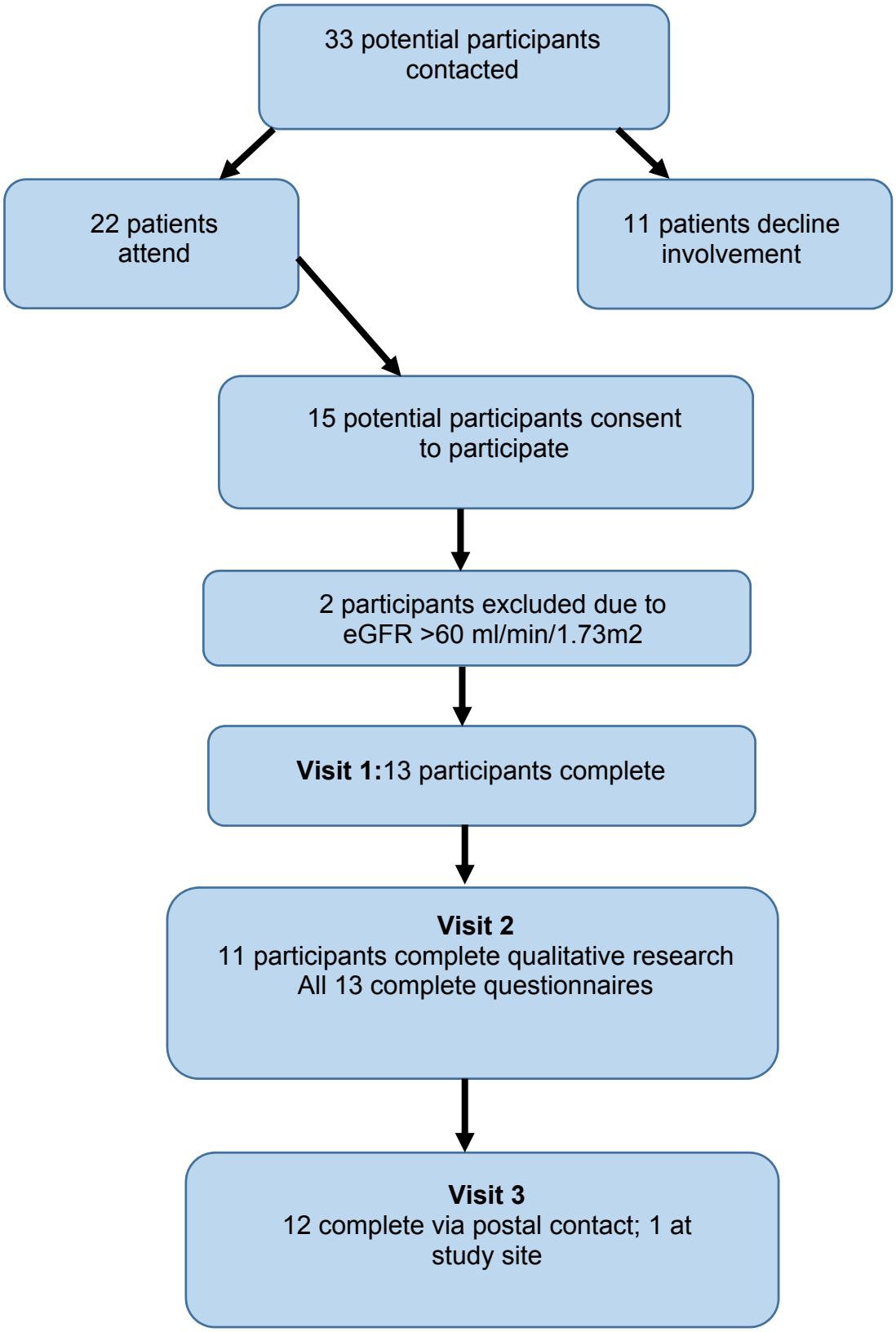

Figure 2: Flowchart indicating participant flow through the study

4.2 Baseline characteristics

The study population was adults, with optimal or slightly above optimal diabetes control (56 mmol/mol [55 mmol/mol -64 mmol/mol]) and in CKD Stage 3 (Table 1). All participants were white British, 23% were female and 76% were male, the majority were retired (85%) with only 15% in employment; which is not unexpected given the median age (70 years [61.2-78.5 years]). Only one of the participants had T1DM (7.7%) while the remaining twelve had T2DM (92.3%). The median duration of diabetes and DKD was 15 (10-23) years and 7 (6-7) years respectively. Table 1 below outlines other biomedical and anthropometric characteristics.

4.2.1 Diabetes management

Diabetes management included a spectrum of medication ranging from monotherapy with oral hypoglycaemic agents (OHA) to triple therapy using insulin in combination with an OHA and a GLP-1 analogue; none of the participants were management through diet and lifestyle alone, 15.4% required one OHA; 7.7% required two OHAs; 46.1% percent of participants required insulin alone ;23.1% required insulin in combination with an OHA and 7.7% required a tertiary regime of insulin, GLP-1 analogue and an OHA.

The median number of anti-hypertensive and dyslipidaemia medication classes used was 3 (2.5-4.0) and 1 (1-1) respectively.

Table 1: Biomedical and anthropometric results (≤ 3 months from baseline)

Variable	Result
HbA_{1c} (mmol/mol)	56 (55-64)
eGFR (ml/min/1.73m^2)	38.9 (34.1-44.6)
Microalbuminuria (mg/mmol) *	1.95 (0.57-2.96)
Proteinuria (mg/mmol) **	185.00 (76.50-348.73)
Total Cholesterol (mm/L)	3.90 (3.35-4.25)
HDL Cholesterol (mm/L)	1.0 (0.80-1.30)
Total:HDL ratio	3.63 (3.20-4.44)
Triglycerides (mmol/L)	3.30 (1.55-3.55)
Systolic Blood Pressure (mmHG)	140 (119-152)
Diastolic Blood Pressure (mmHG)	71 (64-82)
Height (m)	1.72 (1.66-1.81)
Weight (kg)	94.8 (85.2-107.7)
BMI (kg/m^2)	31.9 (29.2-37.2)

Median (interquartile range); *53.8% (N=7) of participants had microalbuminuria;
** 46.2% (N=6) of participants had proteinuria

The majority (77%) of this group with DKD also present with other complications of diabetes as indicated in Table 2. Retinopathy and CVD were the most commonly accompanying co-morbidity, both affecting 61.5% of the study group (Table 2).

Table 2: Complications related to diabetes

Complication of Diabetes	N (%)
Retinopathy	8 (61.5)
Neuropathy	3 (23.1)
Cardiovascular disease	8 (61.5)
Peripheral vascular disease	2 (15.4)
Number of other diabetes complications	
None*	3 (23.1)
One	3 (23.1)
Two	4 (30.8)
Three	2 (15.4)
Four	1 (7.7)

*All have DKD, none refers to those with only DKD

4.2.2 Formal education

Previous formal education varied, as shown in Table 3, with the highest proportion of participants having the highest qualification of work related or other vocational qualification (30.8%) or an apprenticeship (15.4%).

Table 3: Highest level of formal educational attained

Educational Attainment	Participants N (%)
1-4 O Levels, CSEs, GCSEs (any grade), Entry Level, Foundation Diploma	0 (0.0)
NVQ Level 1, Foundation GNVQ, Basic Skills	0 (0.0)
5+ O Levels (passes), CSEs (grade 1), GCSEs (grades (A*-C), School Certificate, 1 A level, 2-3 AS levels, VCEs, Higher Diploma	1 (7.7)
NVQ Level 2, Intermediate GNVQ, City and Guilds Craft, BTEC First/General Diploma, RSA Diploma	1 (7.7)
Apprenticeship	2 (15.4)
2+ A levels/VCEs, 4+AS levels, Higher School Certificate, Progression/Advanced Diploma	0 (0.0)
NVQ Level 3, Advanced GNVQ, City and Guilds Advanced Craft, ONC, OND, BTEC National, RSA Advanced Diploma	1 (7.7)
Degree (for example BA, BSc), Higher degree (for example MA, PhD, PGCE)	1 (7.7)
NVQ Level 4-5, HNC, HND, RSA Higher Diploma, BTEC Higher Level	0 (0.0)
Professional qualifications (for example teaching, nursing, accountancy)	1 (7.7)
Other vocational/work related qualifications	4 (30.8)
Foreign qualifications	1 (7.7)
No qualifications	1 (7.7)

4.2.2 Previous diabetes education

Over half of participants (53.8%) self-reported prior DSE (Table 4). Of those received DSE it was either in the form of individual education from a HCP (42.9%) or a DSE group (42.9%). Only 14.3% reported previous attendance at Diabetes Essentials, the locally

commissioned DSE groups for T1DM and T2DM. Details of the time spent on education and time since this education was received is given in detail in Table 4.

Table 4: Participants previous diabetes education (values are presented as N and percentages of total in parentheses)

	Yes	**No**	**No response**
Have you received previous diabetes education?	**7 (53.8)**	**4 (30.8)**	**2 (15.4)**
Type of education	**Of those who answered "Yes" N=7**	**Total group N=13**	
One to one education with a health professional	3 (42.9)	3 (23.1)	
Diabetes Essentials (Local T2DM Education)	1 (14.3)	1 (7.7)	
Other diabetes education session (e.g. X-PERT programme, DESMOND)	3 (42.9)	3 (23.1)	
Carbohydrate counting and insulin dose adjustment education (e.g. DISC, DAFNE)	0 (0.0)	0 (0.0)	
Other education	0 (0.0)	0 (0.0)	
Length of DM education			
< 15 mins	1 (14.3)	1 (7.7)	
15-30 mins	2 (28.6)	2 (15.4)	
30-60 mins		0	
1-3 hours		0	
Multiple session over a number of days/weeks	4 (57.1)	4 (30.8)	
Time since DM education			
Within the past six months	1 (14.3)	1 (7.7)	
Within the previous year	0 (0.0)	0 (0.0)	
1-2 years ago	2 (28.6)	2 (15.4)	
2-5 years ago	0 (0.0)	0 (0.0)	
Greater than 5 years ago	3 (42.9)	3 (23.1)	
No response	1 (14.3)	7 (53.8)	

4.3 Quantitative outcome measure

4.3.1 Self-management

Table 5 shows the change in SM between each of the three time points. Significant improvements in the SM behaviours listed in Box 1 were observed as a result of the intervention.

Where significance was achieved, it was consistently demonstrated by week six and maintained through to twelve weeks post intervention. As the Likert scale only used a 4 point scale (1-4), the significance change is more effectively demonstrated in the reduction in IQR rather than clearly observed in the median. This suggests individual variability between participant's narrows through the intervention for certain SM actions.

Significant improvements were displayed in the following activities;

- Change lifestyle to avoid worsening of kidney function ($x^2 = 6.320$, $p=0.042$)
- Actively seek information about kidney disease ($x^2 = 13.273$, $p=0.001$)
- Actively seek resources to better control CKD ($x^2 = 13.400$, $p= 0.001$)
- Asking the meaning of blood and urine test results ($x^2 = 7.806$, $p=0.020$)
- Sharing experiences with other patients ($x^2 = 9.235$, $p=0.010$)
- Following healthcare professionals suggestion to adjust dietary habits ($x^2 = 7.786$, $p=0.020$) and to exercise ($x^2 = 6.258$, $p=0.044$)

Neared significant improvement

Finding out the reasons for signs and symptoms of CKD ($x^2 = 5.429$, $p=0.066$).

Box 1: SM behaviours showing significant or trend to improvement as a result of intervention

Table 5: Outcome of CKD-SM questionnaire from baseline to twelve weeks post intervention
Values are median (Interquartile range)

Question	Baseline	Week 6	Week 12	x^2	p value
Pay attention to habits that affect kidney function	3.00 (3.00-4.00)	4.00 (3.00-4.00)	3.00 (3.00-4.00)	0.636	0.727
Adjust food portions and choices when eating out	3.00 (2.00-3.50)	3.00 (3.00-4.00)	3.00 (3.00-3.00)	2.529	0.282
Give up habits harmful to kidneys	3.00 (3.00-4.00)	3.00 (3.00-4.00)	4.00 (3.00-4.00)	1.000	0.607
Adjust things to look after your kidneys to fit different situations	3.00 (2.00-4.00)	3.00 (2.50-4.00)	3.00 (3.00-3.00)	0.200	0.905
Choose food options to avoid harming kidneys	3.50 (3.00-4.00)	3.00 (3.00-4.00)	4.00 (3.00-4.00)	1.000	0.607
Manage CKD to stay healthy	3.00 (2.50-4.00)	4.00 (3.00-4.00)	3.00 (3.00-4.00)	5.120	0.770
Fit the things you need to do to look after your kidneys	4.00 (3.00-4.00)	4.00 (3.25-4.00)	4.00 (3.00-4.00)	2.333	0.311
Adjust lifestyle to maintain kidneys in best condition	3.00 (2.50-4.00)	3.00 (2.75-4.00)	3.00 (3.00-4.00)	1.032	0.597
Participate selectively or avoid certain social activities	3.00 (2.00-4.00)	3.00 (3.00-4.00)	3.00 (3.00-4.00)	2.690	0.261
Change lifestyle to avoid worsening of kidney function **	3.00 (3.00-4.00)	4.00 (3.00-4.00)	4.00 (3.00-4.00)	6.320	0.042
Actively seek information about kidney disease **	3.00 (1.00-3.00)	3.00 (3.00-4.00)	3.00 (3.00-4.00)	13.273	0.001
Actively seek resources to better control CKD **	2.00 (2.00-3.00)	3.00 (3.00-4.00)	3.00 (3.00-4.00)	13.400	0.001
Use different ways to clarify questions about treatment plan	3.00 (2.00-4.00)	3.00 (3.00-4.00)	3.00 (3.00-4.00)	0.250	0.882
Use different ways to solve problems	3.00 (2.00-3.50)	3.00 (3.00-3.50)	3.00 (3.00-3.50)	2.000	0.368

All score range from 1 (never do this activity) to 4 (always to this activity)

α value of $p < 0.05$

** denotes statistically significant result at α-level of 0.05

Table 5: Continued

Values are median (Interquartile range)

Question	Baseline	Week 6	Week 12	x^2	p value
Find out reasons for signs and symptoms of CKD	3.00 (2.00-3.00)	3.00 (2.50-4.00)	3.00 (3.00-3.50)	5.429	0.066
Think about reasons for abnormal blood or urine results	3.00 (2.50-3.50)	2 .00(2.50-4.00)	3.00 (3.00-3.50)	0.889	0.641
Find out possible reasons for high blood pressure	3.00 (2.00-3.50)	3.00 (3.00-4.00)	3.00 (3.00-4.00)	2.077	0.354
Ask the meaning of blood and urine test results **	3.00 (2.00-3.50)	3.00 (3.00-4.00)	4.00 (3.00-4.00)	7.806	0.020
Seek to understand risk factors for CKD	3.00 (2.50-3.00)	4.00 (3.00-4.00)	3.00 (3.00-4.00)	8.063	0.180
Share experiences with other patients **	1.00 (1.00-3.00	2.00 (2.00-2.50)	3.00 (2.00-3.00)	9.235	0.010
Share feelings of helplessness or frustration with other patients	1.00 (1.00-2.75)	2.00 (1.25-2.75)	2.00 (2.00-3.00)	2.882	0.237
Ask family or friends for help when feeling helpless or frustrated	2.00 (1.00-3.75)	2.00 (2.00-3.75)	3.00 (2.00-3.00)	2.385	0.304
Discuss questions or worries with family or friends	2.50(2.00-3.75)	2.50 (2.00-3.75)	3.00 (2.25-3.00)	1.391	0.499
Tell family or friends about CKD treatment plan	2.00 (2.00-4.00)	3.00 (2.00-4.00)	3.00 (2.00-4.00)	1.188	0.552
Follow healthcare professionals suggestion to adjust dietary habits	3.00 (3.00-3.00)	4.00 (3.00-4.00)	4.00 (3.00-4.00)	7.786	0.020
Follow healthcare professionals suggestion to control your weight	3.00 (3.00-4.00)	3.00 (3.00-4.00)	3.00 (3.00-4.00)	0.222	0.895
Follow healthcare professionals suggestion to exercise	2.00 (2.00-3.00)	3.00 (2.50-3.50)	3.00 (3.00-4.00)	6.258	0.044
Follow dietitians suggestions on choosing food	3.00 (3.00-4.00)	4.00 (3.00-4.00)	3.50 (3.00-4.00)	2.333	0.311

All score range from 1 (never do this activity) to 4 (always to this activity)

α value of $p < 0.05$

** denotes statistically significant result at α-level of 0.05

4.3.2 Self-efficacy

Reported levels of SE at baseline are on the higher side of the scale range (Table 6). Statistically significant changes are not apparent in the majority of SE measures however there are a number which do show improvements. Similar to SM results, this improvement appears to be most apparent between pre and post education questionnaires, with maintenance of this improvement through to twelve weeks post intervention. The variable of most significant change is “I can understand the meaning of the CKD-related blood & urine results” which clearly shows an increases between pre and post education (median [IQR] 3.50 (1.25-6.50) pre-education versus 8.50 [8.00-10.00] post-education). Changes in the other variables show improvements in the median value, in combination with clear narrowing of the IQR (Table 6).

Table 6: Outcome of CKD-SE questionnaire from baseline to twelve weeks post intervention

Values are median (Interquartile range)

Question	Baseline	Post education	Week 6	Week 12	x^2	p value
Comfortable telling others that I suffer from CKD	6.50 (2.74-10.00)	8.00 (8.00-10.00)	8.00 (4.50-9.75)	9.00 (5.25-10.00)	6.523	0.089
Seek information to explains CKD related signs & symptoms	7.50 (2.75-9.75)	9.50 (8.00-10.00)	9.00 (8.00-10.00)	9.00 (8.00-10.00)	10.120	0.180
Understand the meaning of the CKD-related blood & urine results **	3.50 (1.25-6.50)	8.50 (8.00-10.00)	9.00 (7.25-9.00)	8.50 (8.00-10.00)	16.515	0.001
Accept the fact that I suffer from CKD	8.25 (8.00-10.00)	9.00 (8.00-10.00)	10.00 (8.00-10.00)	10.00 (8.25-10.00)	2.544	0.467
Understand the risk factors associated with CKD **	8.50 (6.25-9.75)	9.50 (8.25-10.00)	9.00 (8.00-10.00)	10.00 (9.00-10.00)	11.300	0.01
Able to discuss my worries with my family/friends	9.00 (5.25-10.00)	8.50 (5.00-10.00)	9.00 (7.25-10.00)	9.00 (5.75-10.00)	1.838	0.607
Seek help if I am stressed out so as not to affect my disease	6.00 (5.00-8.75)	8.50 (5.25-10.00)	7.50 (6.00-10.00)	8.00 (7.25-9.00)	2.971	0.396
Seek out precautions to prevent my CKD from worsening	7.50 (6.25-9.75)	8.50 (8.00-10.00)	8.50 (8.00-9.00)	9.00 (8.25-10.00)	7.700	0.530
Willing to share CKD SM experiences with other patients	8.00 (7.00-10.00)	8.00 (7.00-10..00)	9.00 (5.50-10.00)	9.00 (5.50-10.00)	1.854	0.603

All score range from 0 (not confident) to 10 (extremely confident)

α value of $p < 0.05$;

** denotes statistically significant result at α –level of 0.05

Table 6: Continued

Question	Baseline	Post education	Week 6	Week 12	x^2	p value
Adjust management of my CKD to fit different situations	8.00 (6.50-9.00)	8.00 (8.00-10.00)	8.00 (8.00-10.00)	8.00 (8.00-10-00)	5.355	0.148
Comfortable asking HPC about my current medical conditions	10.00 (7.50-10.00)	9.00 (8.00-10.00)	9.00 (8.00-9.50)	9.00 (9.00-10.00)	5.692	0.128
Face the challenges of living with CKD	9.00 (7.00-10.00)	9.00 (8.50-10.00)	9.00 (8.00-10.00)	10.00 (9.00-10.00)	6.853	0.077
Actively seek out resources to better control of my CKD **	8.00 (6.50-9.50)	9.00 (8.00-10.00)	10.00 (8.50-10.00)	10.00 (8.00-10.00)	13.145	0.004
Tell my family/friends about my CKD treatment plans to gain support	9.00 (6.50-10.00)	9.00 (5.50-10.00)	8.00 (7.50-10.00)	9.00 (6.50-10.00)	0.484	0.922
Able to control my diet, even if attending a celebration	8.00 (5.50-8.50)	9.00 (8.00-10.00)	8.00 (7.50-9.50)	8.00 (7.50-9.00)	2.758	0.431
Able to manage my CKD as I am maintaining my health	8.00 (6.50-8.00)	9.00 (8.00-10.00)	9.00 (7.50-10.00)	9.00 (7.50-9.50)	7.410	0.060
Take the initiative to tell doctors that I am suffering from CKD	8.00 (8.00-10.00)	10.00 (8.00-10.00)	9.00 (8.50-10.00)	10.00 (9.00-10.00)	5.960	0.114

All score range from 0 (not confident) to 10 (extremely confident)

α value of $p < 0.05$;

** denotes statistically significant result at α –level of 0.05

Table 6: Continued

Question	Baseline	Post education	Week 6	Week 12	x^2	p value
Ask my doctor for advice when questions about medications occur to me	9.00 (8.00-10.00)	10.00 (8.50-10.00)	9.00 (8.50-10.00)	9.00 (9.00-10.00)	2.065	0.559
Choose appropriate type/amount of food when participating in social activities	8.00 (6.50-9.00)	8.00 (8.00-10.00)	8.00 (8.00-9.00)	8.00 (8.00-8.50)	3.063	0.382
Look for information related to CKD through various channels	8.00 (6.50-9.50)	9.00 (7.50-10.00)	10.00 (8.50-10.00)	10.00 (8.50-10.00)	6.065	0.108
Contact HCP for advice when questions occur even without a scheduled appointment	8.00 (5.50-9.00)	9.00 (8.00-10.00)	9.00 (8.00-10.00)	8.00 (7.50-10.00)	5.864	0.118
Adhere to the diet restrictions recommended by the healthcare professionals	7.00 (6.00-9.00)	8.00 (8.00-8.375)	8.50 (7.00-9.00)	8.50 (7.00-9.00)	2.882	0.410
Adjust dietary habits on recommendations of the dietitian/HCP	7.00 (6.00-9.00)	8.00 (8.00-8.75)	9.00 (7.00-9.50)	8.00 (7.50-9.00)	1.402	0.705
Selectively participate in social activities to control of my CKD	8.00 (6.00-8.50)	8.00 (7.00-8.00)	8.00 (7.00-9.00)	8.00 (7.00-9.00)	0.309	0.958
Seek help from family/friends when feeling depressed/frustrated with CKD	8.00 (4.00-9.50)	9.00 (6.50-10.00)	9.00 (7.00-10.00)	8.00 (5.50-9.00)	3.607	0.307

All score range from 0 (not confident) to 10 (extremely confident)

α value of $p < 0.05$;

** denotes statistically significant result at α –level of 0.05

4.3.3 Knowledge

Results of the KiKS show that there is a 93.8% improvement in knowledge outcomes as a result of the education session (Table 7). No reduction in knowledge was displayed and the remaining 6.2% of questions (N=1) remained the same.

The number of people responding correctly to the questions at Visit 2 (6 weeks post intervention) declined from Visit 1 post education (Table 7). Considering percentage correct answers only would suggest that knowledge declined at Visit 2, however this is an increase in non-responses to 68.8% of questions and an increase in incorrect responses in 56.3% of the questions.

Percentage of correct answers at visit 3 (12 weeks post intervention) increased from visit 2 (6 weeks post intervention) in 87.5% of questions, which was in combination with a reduction in incorrect in 37.5% of the questions and a reduction in no responses in 68.8% of the questions. In 75.0% of questions at visit 3, percentage questions correct was higher than baseline. 62.5% of questions at visit 3 are higher than at baseline but not as high as they had been immediate post-intervention.

Table 7: Total scores from the KiKs at four time points showing correct, incorrect and no responses

	Correct				Incorrect				No response			
	Baseline	Post	Visit 2	Visit 3	Baseline	Post	Visit 2	Visit 3	Baseline	Post	Visit 2	Visit 3
On average, what should blood pressure should be?	61.5	84.6	46.2	76.9	38.5	15.4	15.4	23.1	0.0	0.0	38.5	0.0
Medication can help kidney health	76.9	100.0	53.8	92.3	15.4	0.0	7.7	7.7	7.7	0.0	38.5	0.0
Too much protein in urine is not good	53.8	53.8	23.1	38.5	38.5	46.2	38.5	61.5	7.7	0.0	38.5	0.0
What dose GFR mean?	53.8	76.9	53.8	84.6	23.1	23.1	7.7	15.4	23.1	0.0	38.5	0.0
There are stages of CKD	69.2	92.3	61.5	84.6	15.4	7.7	38.5	7.7	15.4	0.0	0.0	7.7
CKD increases heart attack risk	69.2	92.3	46.2	84.6	15.4	7.7	15.4	7.7	15.4	0.0	38.5	7.7
CKD increases risk of death	69.2	84.6	53.8	84.6	23.1	15.4	7.4	7.7	7.7	0.0	38.5	7.7
Kidneys make urine	69.2	76.9	46.2	84.6	30.8	15.4	15.4	7.7	0.0	7.7	38.5	7.7
Kidneys clean blood	53.8	100.0	61.5	84.6	15.4	0.0	38.5	7.7	30.8	0.0	0.0	7.7
Kidneys help bone health	15.4	100.0	46.2	61.5	53.8	0.0	15.4	23.1	30.8	0.0	38.5	15.4
Kidneys help prevent hair lose	84.6	100.0	46.2	61.5	0.0	0.0	7.7	15.4	15.4	0.0	38.5	23.1
Kidneys help red blood cell count	61.5	84.6	61.5	76.9	7.7	15.4	38.5	7.7	30.8	0.0	0.0	15.4
Kidneys help keep BP normal	53.8	75.0	30.8	84.6	30.8	52.0	30.8	0.0	15.4	0.0	38.5	15.4
Kidneys help blood sugars	53.8	69.2	15.4	7.7	38.5	30.8	46.2	69.2	7.7	0.0	38.5	23.1
Kidneys help keep potassium levels normal	76.9	91.8	61.5	76.9	7.7	8.3	38.5	7.7	15.4	0.0	0.0	15.4
Kidneys help keep phosphorus levels normal	38.5	53.8	87.5	53.8	15.4	30.8	12.5	23.1	46.2	15.4	0.0	23.1

Presented as total percentages of responses in each category

4.3.4 Relationship in quantitative outcome measures

Key self-efficacy and SM questions were correlated to identify whether relationships between the two factors exist. These are presented in Table 8 to Table 12 below, which categorised the similar questions into themes.

These results show that for the majority of variables, a significant relationship between the two was not demonstrated. In the 'food related' questions (Table 8), there was a correlation between the SE variable "able to adhere to diet restrictions recommended by HCP" and the SM variable "follow HCP suggestion to adjust dietary habits" (r_s = 0.590, p=0.044). There was a stronger correlation between the SE variable "able to adjust my dietary habits in accordance with the recommendations of the dietitians or HCP" and "follow dietitians suggestions on choosing food" (r_s = 0.875, p<0.001).

In the ability to make adjustments themed questions (Table 9), one correlation exist, which was between "able to manage my CKD as I am maintaining my health" and "manage CKD to stay healthy" (r_s = 0.602, p=0.030).

In terms of risk factor results, no significant correlations were found (Table 10).

Seeking information and support (Table 11) showed significant positive correlations between "actively seek resources to better control CKD" and "I can actively seek out resources to better control of my CKD" (r_s = 0.612, p=0.026) and also between "actively seek information about kidney disease" and "I am comfortable asking HCP about my current medical conditions" (r_s = 0.746, p=0.003).

Strong positive correlations were found in the area of sharing experiences (Table 12). This showed that participants who had high levels of SE in relation to "willing to share CKD self-management experiences with other patients feelings" also rated high levels of "sharing helplessness or frustration with other patients**"**(Table 12) (r_s = 0.724, p=0.005). SM activities of asking friends or family for help when feeling helpless or frustrated and discussion questions or worries with family of friends also correlated highly with their SE counterparts (r_s = 0.813, p=0.001 and (r_s = 0.619, p=0.024 respectively).

Table 8: Correlations between SM and SE variables related to food

Self-Management	**Self-Efficacy**	r_s	p-value
Adjust food portions and choices when eating out	I would be able to choose the type/amount of food appropriate to my disease when participating in social activities	0.202	0.507
Choose food options to avoid harming kidneys	I would be able to adjust my dietary habits in accordance with the recommendations of the dietitians or HCP	0.467	0.108
Follow healthcare professionals suggestion to adjust your dietary habits **	I would be able to adjust my dietary habits in accordance with the recommendations of the dietitians or HCP	0.467	0.108
	Able to adhere to diet restrictions recommended by HCP **	**0.590**	**0.044**
Follow dietitians suggestions on choosing food **	**I would be able to adjust my dietary habits in accordance with the recommendations of the dietitians or HCP ****	**0.875**	**0.000**

r_s : Correlation co-efficient
** denotes statistically significant result at α –level of 0.05

Table 9: Correlations between SM and SE variables related to making adjustments

Self-management variable	Self-efficacy variable	r_s	p-value
Give up habits harmful to kidneys	I would actively seek out precautions to prevent my CKD from worsening	0.496	0.850
Adjust things to look after your kidneys to fit different situations	Would selectively participate in social activities (e.g. attending dinners or gatherings) in order to control of my CKD	0.391	0.186
Manage CKD to stay healthy	**I would be able to manage my CKD as I am maintaining my health**	**0.602**	**0.030**
Fit the things you need to do to look after your kidneys	I can face the challenges of living with CKD	0.108	0.726
Adjust lifestyle to maintain kidneys in best condition	I would be able to adjust management of my CKD to fit different situations	0.460	0.114
Participate selectively or avoid certain social activities	Would selectively participate in social activities (e.g. attending dinners or gatherings) in order to control of my CKD	0.246	0.417

rs : Correlation co-efficient

** denotes statistically significant result at α –level of 0.05

Table 10: Correlations between SM and SE variables related to risk factor results

Self-Management	**Self-Efficacy**	r_s	p-value
Think about reasons for abnormal blood or urine results	I would actively seek out precautions to prevent my CKD from worsening	0.673	0.120
Find out possible reasons for high blood pressure	I can actively seek information to explains CKD related signs & symptoms	-0.064	0.837
Ask the meaning of blood and urine test results	I am comfortable asking HPC about my current medical conditions I can understand the meaning of the CKD-related blood & urine results	0.429 0.210	0.143 0.491

r_s : Correlation co-efficient

α –level of 0.05

Table 11: Correlations between SM and SE variables related to seeking information & support

Self-Management	**Self-Efficacy**	r_s	p-value
Actively seek information about kidney disease	**I am comfortable asking HCP about my current medical conditions**	**0.746**	**0.003**
Actively seek information about kidney disease	Would take the initiative to contact HCP for advise whenever any questions about my disease or treatment occur to me, even without a scheduled appointment	0.457	0.117
Actively seek resources to better control CKD	**I can actively seek out resources to better control of my CKD**	**0.612**	**0.026**
Use different ways to clarify questions about treatment plan	I am comfortable asking HPC about my current medical conditions	0.532	0.061
Use different ways to solve problems	I can actively seek out resources to better control of my CKD	-0.29	0.925
Use different ways to solve problems	I would take the initiative to contact the healthcare professionals looking after me for advice whenever any questions about my disease or treatment occur to me, even without a scheduled appointment	0.272	0.369
Find out reasons for signs and symptoms of CKD	I can actively seek information to explains CKD related signs & symptoms	-0.60	.846
Use different ways to clarify questions about treatment plan	I am comfortable asking HPC about my current medical conditions	0.532	0.061

r_s : Correlation co-efficient

** denotes statistically significant result at α –level of 0.05

Table 12: Correlations between SM and SE variables related to sharing experience

Self-Management	Self-Efficacy	r_s	p-value
Share experiences with other patients	I am willing to share CKD SM experiences with other patients	0.508	0.706
Share feelings of helplessness or frustration with other patients	**I am willing to share CKD SM experiences with other patients**	**0.724**	**0.005**
Ask family or friends for help when feeling helpless or frustrated	**Can actively seek help from my family or friends whenever I am feeling depressed or frustrated with my CKD**	**0.813**	**0.001**
Discuss questions or worries with family or friends	**I would be able to discuss my worries with my family/friends for solutions**	**0.619**	**0.024**
Tell family or friends about CKD treatment plan	I can tell my family/friends about my CKD treatment plans to gain support	0.0504	0.079

rs : Correlation co-efficient

** denotes statistically significant result at α –level of 0.05

4.3.4.1 Correlation between total knowledge score and SM

There was a moderate positive correlation between total knowledge and two of the SM statements at week 12 (Table 13). Paying attention to factors which affect kidney function (r_s = 0.579, p=0.039) and adjusting food portions and choices when eating out (r_s = 0.558, p=0.047) were both correlated to knowledge scores at week 12.

Table 13 shows a lack of correlation between total knowledge score and other SM variables when each of the SM variables were correlated with total knowledge score at week 12.

4.3.4.2 Correlation between total knowledge score and SE

No correlation was found between any of the SE and total knowledge score at week 12 (Table 14).

Table 13: Correlations between total knowledge score (percentage questions correct) and self-management activities at Week 12

Self-Management Activity	r_s	p-value
Pay attention to habits that affect kidney function **	*0.576*	*0.039*
Adjust food portions and choices when eating out **	*0.558*	*0.047*
Give up habits harmful to kidneys	0.332	0.268
Adjust things to look after your kidneys to fit different situations	-0.257	0.396
Choose food options to avoid harming kidneys	0.064	0.836
Manage CKD to stay healthy	0.289	0.339
Fit the things you need to do to look after your kidneys **	*0.612*	*0.026*
Adjust lifestyle to maintain kidneys in best condition	-0.137	0.656
Participate selectively or avoid certain social activities	0.024	0.937
Change lifestyle to avoid worsening of kidney function	-0.083	0.787
Actively seek information about kidney disease	0.182	0.552
Actively seek resources to better control CKD	-0.171	0.576
Use different ways to clarify questions about treatment plan	-0.250	0.411
Use different ways to solve problems	0.052	0.866
Find out reasons for signs and symptoms of CKD	-0.344	0.250
Think about reasons for abnormal blood or urine results	0.135	0.660
Find out possible reasons for high blood pressure	0.212	0.486
Ask the meaning of blood and urine test results	-0.478	0.099
Seek to understand risk factors for CKD	-0.540	0.057
Share experiences with other patients	-0.250	0.411
Share feelings of helplessness or frustration with other patients	0.255	0.400
Ask family or friends for help when feeling helpless or frustrated	-0.072	0.814
Discuss questions or worries with family or friends	-0.054	0.861
Tell family or friends about CKD treatment plan	-0.111	0.719
Follow healthcare professionals suggestion to adjust dietary habits	0.463	0.137
Follow healthcare professionals suggestion to control your weight	0.314	0.296
Follow healthcare professionals suggestion to exercise	0.212	0.486
Follow dietitians suggestions on choosing food	0.127	0.680

r_s : Correlation co-efficient

****** denotes statistically significant result at α-level of 0.05

Table 14: Correlations between total knowledge score (percentage questions correct) and self-efficacy at Week 12

Self-Efficacy	r_s	p-value
Comfortable telling others that I suffer from CKD	-0.238	0.433
Seek information to explains CKD related signs & symptoms	-0.142	0.643
Understand the meaning of the CKD-related blood & urine results	0.163	0.595
Accept the fact that I suffer from CKD	0.017	0.956
Understand the risk factors associated with CKD	-0.190	0.952
Able to discuss my worries with my family/friends	-0.240	0.429
Seek help if I am stressed out so as not to affect my disease	-0.148	0.628
Seek out precautions to prevent my CKD from worsening	-0.191	0.532
Willing to share CKD SM experiences with other patients	0.372	0.211
Adjust management of my CKD to fit different situations	0.086	0.781
Comfortable asking HPC about my current medical conditions	-0.136	0.658
Face the challenges of living with CKD	-0.407	0.167
Actively seek out resources to better control of my CKD	-0.168	0.584
Tell my family/friends about my CKD treatment plans to gain support	0.025	0.935
Able to control my diet, even if attending a celebration	0.075	0.808
Able to manage my CKD as I am maintaining my health	0.419	0.154
Take the initiative to tell doctors that I am suffering from CKD	-0.407	0.167
Ask my doctor for advice when questions about medications occur to me	-0.267	0.377
Choose appropriate type/amount of food when participating in social activities	-0.056	0.855
Look for information related to CKD through various channels	0.049	0.873
Contact HCP for advice when questions occur even without a scheduled appointment	0.148	0.630
Adhere to the diet restrictions recommended by the healthcare professionals	0.489	0.107
Adjust dietary habits on recommendations of the dietitian/HCP	0.366	0.218
Selectively participate in social activities to control of my CKD	0.352	0.239
Seek help from family/friends when feeling depressed/frustrated with CKD	-0.042	0.891

r_s : Correlation co-efficient

α-level of 0.05

4.4 Qualitative

A total of eleven semi-structured qualitative interviews (QIs) were undertaken; ten were in the form of face-to-face interviews, nine as individual interviews and one was a paired interview with a husband and wife (the husband had attended the diabetes education session). One of the QIs was conducted as a telephone contact as the participant was unable to attend the study venue due to family commitments. Interviews lasted between 20 minutes and one hour, and consent was obtained from the participant for the QI to be audio recorded.

Overall the participant's responses towards the sessions were positive. A number of themes emerged from the data, which included reinforcement, raising awareness, behaviour changes, coping, negative impacts, and suggested changes. Themes and sub-themes are presented below (Table 15), with quotes to illustrate key points.

Table 15: Themes and direct participant quotes from qualitative interviews

Theme	Comment	Direct participant quote
Session Delivery and Content	The delivery and content of the session was viewed in a positive light by all participants, with the majority of participants reporting that the information was provided at the right level, and that there was enough opportunity to ask questions and gain clarity if required.	*"It was well presented, all the slides that were there were very instructive and the way it was put over to us was in a way that anybody could understand"* *"It wasn't too technical. And the slides were explaining what your kidneys do and things like that, there was not a lot of science in there it was all very basic, you know this is how it cleans your blood and this is what happens when things go wrong"* *"I think [the Dietician] gave a really comprehensive session, she was really good. Very very good in fact. And she made it so clear for them, I thought she give amazing, she was a good dietician, let me say that. If I was starting out it was really helpful let's put it that way"*
	The group format of the DSE was regarded as positive by most participants. Some participants felt that certain group members were asking a lot of questions or taking up the time of the facilitator, but on the whole the group setting was positive.	*"You're all there doing it together cos at times you can think am I the only person, and it makes you realise that there's other people with the same problems that you've got, so yeah that was good that"*

Table 15 (Continued)

Session Delivery and Content (continued)	Participants also suggested that the manner in which the course content was delivered had helped their understanding.	*"It was well presented, all the slides that were there were very instructive and the way it was put over to us was in a way that anybody could understand"* *"[the course facilitator] was so informative and you know there was several people there that didn't know certain things and I thought you're giving easy how can I say, easy for them to understand, she did make it very clear to us, it was very good actually"*
	One participant explained how this session reminded him there was support there if ever he needed it.	*"Well knowledge of, you're not just, blaming yourself for everything, there's always somebody at the end of a telephone to help, so if I, you know if different things happen, you can ring somebody even if it's here, if you can't get them on they, you know straight away, leave a message they'll ring you back."*

Table 15 (Continued)

Reinforcement	All participants acknowledged having prior understanding of DKD and shared details of their lifestyle and health-related behaviours. Many participants described the education as reinforcing the information that they had previously received from HCPs in previous appointments. They felt reassured that they were following a healthy lifestyle. Some of the participants went on to describe how the sessions had helped them to feel empowered to learn that they had been leading the healthy lifestyle that was advocated within the session.	*"Because we used to go regularly to the clinic, I think everything we do now is a matter of course, because you do it that much….you feel good because you knew the things you were doing were okay"* *"I think really the messages I took were reinforced from what I've had from the dietitians and diabetic team previously, is to be aware when you're going to have food and to be aware of what the contents of that food have in so much of the salt, the different types of fats, the sugars, the carbohydrates that will affect the diabetes and also the kidneys"* *"It was good to see the explanation again about what your kidneys do and where things can go wrong and the basics you know of what you've got to do…. I was quite reassured you know that apart from slipping off the wagon every now and then I was sort of doing the right things really"* *"I know I've got kidney problems and I know I've got diabetes but it helped to link to two in my mind, to reinforce, you know particularly things about salt, what you eat you know and how that can affect your kidneys"* *"Although there were things reinforced by the education session it was reinforcement instead of new knowledge"* *"In many ways what the sessions have taught me is to reinforce what I've already been thinking"* *"She made me feel okay because I was following the right pattern as far as I could understand on the charts and the information she was giving us on it"*

Table 15 (Continued)

Awareness	Increased awareness of the impact of the condition on lifestyle was another theme identified. Many described how the education session had improved their understanding of their condition, and the impact that this had on their lifestyle. Participants also described what they felt they learn during the session.	*"… look out for infections that could alter my lifestyle, to look out for any pain over me kidneys, and just basic things really that you don't associate with what goes on. Just made you aware more of it."* *"I learnt a lot from the diet side about it like cos I knew about how many calories you're meant to have, how much fat you're meant to have but I learnt a lot more about the sugars and the carbs…a lot of it, I already knew before but there was just little bits taken away, like basically how the kidneys worked as well."* *"I've had it years anyway so I already know to watch what I eat but it was the actual numbers, learning about the blood pressure that I found useful"* *"Since coming on this course, it's not so much going over on food and eating normally but I'm more aware now to look at everything we're going to eat"* *"My diabetes control is certainly a lot better now than it was because I understand more"* *"It made me realise when you look at some tins they are very misleading, and I learnt that in the class we had that day, and I started to take more notice of when we go shopping and have a meal; I will now look at the salt content and the other contents and I know that a lot better now"* *"Learning more about the carbs and the food you eat and to control your diabetes, and this one with the kidneys which I didn't know anything about; well I thought I did but I didn't when I came to answer the questions I didn't know the answers"*

Table 15 (Continued)

Behaviour Change	When asked to describe any changes that they had made to their lifestyle, since attending the course, and many participants were able to detail changes that they had made.	*"I try and watch fatty foods, and if I'm cooking anything I watch what I cook."* *"I stopped using salt in my cooking anywhere and I thought I'm cooking without salt so if anyone wants to eat my food the salt is on the table and they can put it on there so that's what I do now, and I just use herbs"* *"[The course] has encouraged me to watch what I eat, how I eat it… Instead of been up here with the portions I've cut em virtually in half from what I used to do"* *"I used to enjoy on a Sunday a sausage or something, I now don't, and I make sure if we have the bacon that it's always grilled and grilled on wire so the fat drips off them, and the gravy as I say that's been cut out completely."* *"At one stage I was having a ham and tomato bun and a banana each lunch time without fail. I learnt that bananas are high in potassium, and my potassium is high, and tomatoes are high in potassium, so, cut that down."*
	One participant described the benefit of appropriate diabetes management in aiding their CKD and this was seen as a positive learning outcome as it aiding anxiety levels.	*"Well I think the key message is that although I have a kidney dysfunction that I needn't get into worrying about that, the key message is that I can look after my diabetes, and I can look after my kidney dysfunction" (Participant 3)*

Table 15 (Continued)

Behaviour Change (continued)	Others described the impact that the behaviour change had had on their lives, and explained the effect the implementation of the changes had for them.	*"It's the flexibility of being able to go out, and you say right I can do this do that and obviously keep my eye on this that and the other, and it's helpful when you, otherwise your life is circled around your house and diet, and if you know exactly what you're doing you know it's helpful, you at least have some kind of life"* *"I feel a lot better and it's not just me saying that. People have stopped me and said I look a lot better, I had someone this morning say to me you look at lot better. So I'm very pleased"*
Anticipated changes	Many detailed further changes that they would benefit from. Motivation and willingness to change were sub-themes related to the issue of behaviour change, and issues of control and personal responsibility were raised by a lot of the participants, when discussing the changes that they knew that the needed to make.	*"I'd like a lot of help with trying to get meself sorted…Try and be as active as possible but I know I never might not be, but try and do things"* *"It's putting it into practice. The awareness is there now, its converting that awareness into actual reality."* *"That information was good, it was clear, it highlighted risks, but it's making that next step of from the information into reality"* *"Well much of it I already knew, and as a diabetic, to follow some of the procedures I shall find rather difficult. Personally the way I look at it myself, I keep off refined sugars as much as possible, and regards anything else, I virtually ignore it."* *"Well me and me wife have started dieting, well we've been dieting for months and its bloomin hard but we'd sort of already started that. I think exercise is the next tick box for me….I used to walk me neighbour's dog but that's stopped now and I used to be a keen cyclist….it's just getting back into the routine"*

Table 15 (Continued)

Anticipated changes	One participant described how the responsibility to change lay with him; he acknowledged the support HCPs can provide and resources, however his statement makes the SM nature of the condition apparent.	*"You realise if you're not going to do anything about it it's a waste of the doctors time, money, efforts, everybody right the way through, if you're going to sit there and vegetate or you get the chance of a new lease of life, if you don't take it you're an idiot."*
Barriers to change	Participants recognise elements of their management that they wish to change or improve on, however identify difficulties in implementing and making behavioural changes. Some challenges were related to issues of motivation and overcoming habits, other participants spoke of how they felt the challenges were related to their health conditions.	*"I've been able to take charge. Yes that's rights. Sometimes I wish I hadn't got to, cos I look at the bars of chocolate and I look at the cakes and I think oh dear, sometimes I want to slip up"* *"I'll lose weight and then I'll put it back on and put it back on some more, so in terms of is it answering, it's not unlocking my problem"* *"The only thing that hinders me is the evening, because I'm so tired and I sit there and think I want to eat. But now I don't tend to eat except I'll have a bag of crisps and my Horlicks. Every night have me bag of crisps and I have me Horlicks"* *"…taking more exercise, I've thought about it, but that's as far as it's got…. I'm aware of it. I don't really plan because again, there are other things: if I start walking a lot, or speed up my walking then I finish up with problems with my breathing and my circulation; because I've got poor circulation, it doesn't get round, and I finish up with pain in my legs and my hips. You know."*

Table 15 (Continued)

Support	The role of family and friends was a consideration for the majority of participants; for many this was a positive influence in aiding them to make and maintain lifestyle changes and help motivation levels.	*"With the help of my wife, I know how to look after my diabetes." (Participant 3)* *"I've got a lot of friends and my sister lives next door so I've got her as well. My friends are all members of arthritis care and they help a lot. One of them has recently been diagnosed as diabetic herself, and she's doing diet only, so we often have a chat."* *"[Support from my wife is] helpful, yeah, yeah it is….we have a bit of a competition every week when we get weighed you know and things like that."*
	During the paired interview, a spouse identified reasons for her husband's weight gain and discussed how she needed to support her husband to lose weight.	*"I think I may need to sort him out for losing a little bit of weight because he has, it could be with it being the winter you know, and you're eating different kinds of foods, so he needs to lose a little bit of weight at the moment, and he's inactive as well" (wife of diabetic husband)*

Table 15 (Continued)

Support (Continued)	In contrast to the supportive role of family and friends, others described how they lacked the support and encouragement they needed, particularly from family members, and the negative connotations they felt this had on their ability to make necessary behavioural changes.	*"Just the encouragement to do it without somebody saying well you can do it if you try, you know somebody to say well done, you've done that. Instead of somebody saying well you don't do much, you don't do that. You can only try."* *"I think it would help if my wife would buy into the process. I work away from home Monday to Thursdays but if she could be part of the whole piece then it would make life a lot easier in that sense"* *"I: where would that support come from? Are you thinking clinicians or family members?* *P: no, family members, cos family members are very…put you down some times."* *"I'm not actively thinking about it [making behaviour change]. If my wife was more actively involved, and that sounds like a cop out really, but there would be, I would feel that would be a real step forward."*

Table 15 (Continued)

Coping	Participants described their day-to-day experiences of living with DKD and detailed the challenges they often faced in learning to live with their condition. Eating out and shopping were often mentioned during interviews, where participants spoke about no longer eating out or the extra steps they had to ensure when eating out to ensure that their dietary requirements were met, and the extra time taken checking food labels when shopping.	*"We don't eat out as much now…it's something we don't do really, which is a shame, we do occasionally but it's a shame, I steer clear of that a bit" (Participant 3)* *"For me to do a weekly shop it takes around two hours…. going round the store, checking the labels, checking what I'm buying…. and making sure what I've got and sort of working out well I can't buy that but I can buy that make, it depends on the make. Normally I have a hefty bill because I have to buy branded stuff" (Participant 8)* *"When you're shopping you select food from the shelf, you look at the labels and stuff, I think you're a bit more focused on that" (Participant 3)*

Table 15 (Continued)

Coping	Many participants described the challenges that they faced in having to deal with multiple conditions, and the conflicting advice and information that they have to process and act upon.	*"So I had two diets and I had to check em both because not always what's on one is good for the other"* *"Now and again I see the diabetic nurse at the doctors, but she's not happy seeing me because I've got such a lot of complicated things wrong with me" (Participant 5)* *"Sometimes you go to one clinic and they say one thing and you go to another clinic and they say something entirely different and you think to yourself well what am I doing wrong, and then of course, when you ask them a question they say oh right, and you tell them I've been to this clinic and they said this, they say well stick to that" (Participant 8)* *"You read one thing that says if you've got this complaint which I've got it says eat avocado cos it's good for you and then you read something else and it says don't eat avocado so you know it can be a bit of a trial at times" (Participant 10)*

Table 15 (Continued)

Empowerment - biomedical	A common theme was the lack of sharing of biomedical results between HCP's, particularly GP's and patients. Participants were not informed of results and there is the suggestion that when results were not shared with the participant that this lead to the assumption that the test result were positive/good and didn't require action. For some participants they felt that the course had prompted them to ask more questions of their GP regarding biomedical results.	*"I've come to realise that as a result of that course, we had a blood test taken and my readings were not very good and of course I had had quite a number of blood tests where my doctor had said they were steady, they were okay, but they were worse than the readings that I'd had here, when I'd been called back for another blood test." (Participant 6)* *"I just had to do another blood test, we'll have another blood test, so they did another blood test and I was okay, I wasn't called in for anything. I wasn't told anything so, you know it's what you do, if you don't hear anything back, you think it's okay, which it probably is." (Participant 3)* *"I mean my GP just did these tests and he didn't tell me and then he just started doing these test for eGFR. I said what's that, I had to go online to find out" (Participant 5)* *"[The course] prompted me to go back and ring me GP up and get me last readings, because they're not very good at communicating that really, I mean I have blood tests here every four months, but I don't ever get feedback unless there's something wrong, I just take it well you know if I haven't heard anything then that's alright, but it did prompt me , and it'll probably prompt me in future, cos I get me blood tested every time I come and I only see me own GP once a year, it will prompt me to ring them up and get confirmation of what the results are."*

Table 15 (Continued)

Reality	A small number felt that the session brought home the severity of DKD. One participant described how the module emphasised the seriousness of the condition, and the detailed risk factors combined with his lifestyle resulted in a realisation which affected his SE. He describe a preference to receive information prior to prepare for the content.	*"[It was the] starkness of when you see, like for me, when I ticked all the boxes, and like I said earlier, I'd probably been told but it didn't register, that I'm in serious trouble in effect. It's that, and that deflected from some of the content for the session…I did feel rubbish about meself" (Participant 4)* *"Looking back, I realised I went very quiet and within myself because it hit home to me rather starkly where I was, so I found that very hard and very difficult, and I've struggled with it since, in fact what happened with me when I worry about things I eat, so a consequence from that, rather than it helping me, because of me, I finished up, I've put on quite a lot of weight since that event" (Participant 4)*
	Another participant described how he had not had very much information from his GP about his DKD, and described his surprise at having been invited to participate in the education session.	*"I received it out of the blue, an invitation, I'm not sure but I think because information must have come here from my GP and I'd had some information that I had some dysfunction with my kidneys, but nothing very much and it was a bit of a surprise really…* *"There'd never been a focus at the surgery on a kidney dysfunction. All that happened was, I had a blood test and I got called in, you know, come and see the doctor, and I was told my kidney was showing up some negative stuff and that was that. And then after that I get called to this" (Participant 3)*

Table 15 (Continued)

Further Support	When asked whether they would benefit from further support, many the majority felt they received adequate support from routine appointments with HCP's. However, a common theme was living with multiple LTCs and felt they could benefit from more tailor-made practical advice to help them to make healthy lifestyle choices.	*"I tell you what there isn't enough is diet sheets, and I don't mean information that you should be on a diet I mean you know putting diet sheets and have two diet sheets together especially for kidneys, where you've got one for low potassium, and one for you know, the sugar diet, the diabetes ones, so issuing everybody with two of those would be a good idea I think." (Participant 2)*
	Others recognised changes in management can occur therefore warranting additional information and future education and to reinforce previous education and share new advice.	*"Well I just hope they repeat it, if they've got the resources to do it, I think this is quite a forward looking unit to be honest and I hope they repeat it, if I'm honest with you. You know I'm not saying do them every six months or whatever but once a year or once every eighteen months or whatever just to kind of remind people" (Participant 10)*

Table 15 (Continued)

Further Support	The participants who had found the session difficult to process due to realisation of his risk factors and the implications for his health, suggested that he would benefit from follow up sessions, delivered on an individual basis. Again the importance of support, not only from clinicians but social support is highlighted in the inclusion of his spouse in being able to utilise further support.	*"Yes it would be 1-1 sessions. The session that we had was good, there was four of us, so for that type of event that was spot on, but for me now to move forward I really feel as if I need some one to one or one to two with me and my wife, that would possibly help" (Participant 4)*

5. Discussion

5.1 Summary

This research indicated that a standalone DSE disease-specific module has a positive impact on patient self-care, represented by improved knowledge, and significant increased levels of SM and SE related to DKD management. This is reinforced by qualitative findings which demonstrate the positive impact of the module, which provides supporting evidence of actual changes as a result o the module.

The results illustrate the need for partnership between HCPs and patients to aid understanding and management of DKD. Qualitative findings highlight the lack of communication from HCP in sharing information pertinent to DKD results, while the quantitative findings show an increase in patient SE and SM in relation to biomedical results once they are made aware of the biomedical tests in DKD and the Implication of these. The importance of social support is evident through quantitative findings showing significant strong correlations between SE and SM in relation to sharing of worries and seeking helping from family and friends and which is further emphasised by qualitative finding showing the positive and negative implication of support depending on the support available or lack thereof, on patients SM.

The three month follow-up period was sufficient to demonstrate that ask time from education progresses, a decline in knowledge is demonstrated. This is also supported by qualitative findings which suggest that potential awareness of the SM activities were known to the patients prior to the intervention, with the education acted to reinforce this awareness and as a result prompt re-engagement or initiation of SM activities.

5.2 Participant's characteristics

The majority of the participant population (92%) had T2DM; which reflects the national average of approximately 10% and 90% for T1DM and T2DM respectively (Diabetes UK, 2014). Table 16 highlights that the study cohort represents a well-managed DKD population, given median biomedical results for HbA1c, BP and cholesterol shows optimal control is achieved in the majority of the cohort. This is further emphasised when consideration is given to the percentage to the local population who achieve treatment target

Table 16: Percentage of people with diabetes who achieve treatment target in NHS West Cheshire and median values (IQR) for biomedical measures of the study cohort

Measure	**Target**	**West Cheshire[1]**	**Study cohort**
HbA1c	<58 mmol/mol	66.4%	56 (55-64) mmol/mol
Blood Pressure	≤140/80 mm Hg	73.6%	140/71 (119-152/64-82) mm Hg
Cholesterol	< 4mmol	44.2%	3.90 (3.35-4.25) mmol
All measures	All of above	41.5%	

[1]Percentage of people with diabetes in West Cheshire locality achieving treatment targets (Source: Health and Social Care Information Centre, 2014*)*

The National Diabetes Audit (NDA) identified that older adults with T2DM have the highest levels of achieving treatment targets (Health and Social Care Information Centre, 2014*).* While those in the 65 to 79 years age range for T1DM and T2DM are more likely to receive

all eight care process identified by NICE guidelines which includes measurement of HbA1c, BP, cholesterol, urine albuminuria and serum creatinine (NICE, 2004; NICE, 2008).

When this is compared to the study population, it suggests the participants are those most likely to be receiving healthcare essentials and more likely to be achieving treatment targets, given 92.3% had T2DM and the median age was 70 years (IQR 61.2-78.5 years).

Access to diabetes healthcare essentials is an important consideration as research suggests that this practice leads to greater likelihood of treatment target achievement (Persell et al., 2010). A cross sectional study found that those who received cholesterol and microalbuminuria testing, and a foot examination had better HbA1c results (Persell et al., 2004). It must be acknowledge that the authors categorised better HbA1c as 9.5% (80 mmol/mol) or less, which is higher than current treatment target of <58 mmol/mol (7.5%). However, it does suggest that better HbA1c control, albeit not optimal control is achieved in those receiving more of the healthcare essentials.

Given the chronic progressive nature of diabetes, access to the healthcare essentials may hold understandable benefits given that the changing dynamic of diabetes often necessitates continuous monitoring, hence the fifteen healthcare essentials (Diabetes UK, 2011) and adjustment of management practice in order to identify when current management no longer suffices, to aid achievement of optimal control.

5.3 Impact of education on SM

5.3.1 Biomedical results

An area of significant change in the current study was in relation specifically to the biomedical measures of the healthcare essentials. Both SE and SM activities related to understanding and asking the meaning of blood and urine results demonstrated significant improvements. Considerable focus was given to this in the QI (for examples see Table 15 section “Empowerment-biomedical”)

This is a positive outcome of the study given as it shows that the education session can support participants to develop SM behaviours and enhance SE, which can be utilised in DKD self-care.

Other research in this area suggests that knowledge regarding clinical measures results in better diabetes control (Polonsky, Zee, Yee, Crosson & Jackson, 2005; Beard, Clark, Hurel & Cooke, 2009). Education to improve familiarity and understanding of biomedical measures incorporated in diabetes care has been shown to significantly improve HbA1c and SM (Polonsky et al., 2005).

Other studies contrast this and suggest that knowledge of HbA1c alone is not sufficient to improve diabetes SM and SE (Skeie, Thue, & Sandberg, 2001; Heisler, Piette, Spencer, Kieffer, & Vijan, 2005). Heisler et al., (2005) found that good communication with HCP’s and higher levels of formal education background were associated with better laboratory measured HbA1c. While Skeie et al., (2001) found that those who self-report better knowledge about HbA1c are those who have longer duration of diabetes and preform greater self-monitoring of blood glucose, which is proposed to be as a result of greater levels of knowledge accumulation through years of diabetes management. In contrast to Polonsky et al. (2005) no difference in actual HbA1c was found for those who reported higher or lower levels of general HbA1c knowledge (Skeie, et al., 2001). This study did not

investigate how accurate participants self-reported HbA1c was compared to their actual laboratory measured HbA1c value via comparison to medical record. This would add extra value to the study as it would identify whether a relationship exists between reported knowledge and a relatively unbiased biomedical result exist, rather than relying on self-reported results which may be incorrect.

Overall this research suggests that in isolation knowledge of HbA1c is insufficient to impact actual results, however combined with education to improve knowledge, SE and SM skills and in partnership with HCP, it can improve HbA1c outcomes (Beard et al., 2009; Heisler et al., 2005; Polonsky et al., 2005. Skeie, et al., 2001).

This is a consideration of recent national incentives which encourage awareness and understanding of targets in order to support SM (Coulter, Roberts, & Dixon, 2013). The NHS Year of Care model aims to create a partnership between the HCP and the person with diabetes (or other LTCs) to aid SM (Coulter et al., 2013). This has positive cost implication for the NHS (Wanless, 2002) and provides individuals with the support to increase their confidence in self-care (Coulter et al., 2013).

A value of the present study is that the module encourages engagement with receiving the diabetes healthcare essentials outlined by Diabetes UK (2011) particularly in relation to DKD, namely HbA1c, BP, lipid profile, microalbuminuria and eGFR. The may be a benefit of this education, considering participants show a significant improvement in understanding of the laboratory results, and increased confidence in asking the meaning of blood and urine test results emphasised by qualitative findings which suggest participants are more likely to ask for and discuss results with their HCP (Table 15).

The measurement of long term changes in clinical outcomes measures were not permitted in the current research. However the research outlined above, suggests that awareness of targets can be an aid to progressing actions of self-care into improvements in metabolic outcomes.

5.3.2 Correlation between outcome measures

Interestingly there were no corrections between SM “ask the meaning of your blood and urine test results” with SE “I can understand the meaning of the CKD-related blood & urine results” despite both independently showing significant improvements. Similarly neither of these SM or SE variables showed any relationship with total knowledge scores despite individual knowledge questions relating to BP and GFR showing improvements through the education session.

The present study was able to demonstrate improvement in SE and SM specific to following dietary recommendations, seeking resources to aid CKD management and discussing experiences, problems and concerns with family members and friends. Further to this a strong positive correlation were found between SM and SE related to following dietary advice. This is in keeping with other studies into SE and SM behaviours in diabetes and CKD which show individuals with higher levels of SE have higher levels of SM behaviours (Al-Khawaldeh et al., 2012; Curtin et al., 2008; Knight et al., 2006). Al-Khawaldeh et al. (2012) demonstrated correlations between diet, exercise, blood sugar testing and medication taking SM behaviours and SE with respect to these behaviours; this study did not explore biomedical results. This suggests self-care requires an emphasis on empowering people with diabetes to aid the SM actions.

Interestingly Steed et al., (2005) examined outcomes from a three month education intervention, and found that education resulted in improvement in exercise and blood glucose monitoring SE and these two factors had the greatest change in SM behaviours. This is a similar relationship in different areas to the current research, however no correlation outcomes between SE and SM behaviours was presented by Steed et al., (2005).

In the current research, it would be useful for the intervention to promote a greater degree of partnership in care-planning and questions around treatment, particularly if it is aids adherence to the treatment plans. Care plans for diabetes are multi-factorial and complex, differing for each individual and with difference circumstances for each person. McNab (1997) identified problems in adherence including multiple SM behaviours, required on a daily basis, potentially alongside other health conditions and also a lack of specific instruction on targets from HCPs. The present study suggests some improvement has been made, represented by correlation between seeking information about CKD and asking HCPs about current medical condition, and further supported by the QIs, for example,

> *"[The course] prompted me to go back and ring me GP up and get me last readings, because they're not very good at communicating that really"*

This suggests that improvements in SE and as a result SM behaviours have been achieved, with similarities to other research in the area but present inconsistencies in certain areas regarding to the relationships between certain SE and SM activities.

The present study also, found no correlation between either of the SM behaviours seeking information or using different means of clarifying questions with the SE measure contact HCP to seek advice. Curtin et al., (2008) identified weak correlations between SE and

elements of SM behaviours relating to communicating with HCPs, seeking out sources of information and daily practical self-care activities. No correlation was found with self-advocacy which was related to seeking a second opinion and asking for improvements or change to regimes (Curtin et al., 2008). Curtin et al. (2008) suggest that self-advocacy as described in their questionnaires, is of least relevance to individuals with CKD. However, perhaps it is a reflection of health care provision that the HCP "knows best" and as such individuals may be less likely to question practices.

5.3.3.1 Partnership

Improvements in SM and SE were demonstrated in actively seeking information about CKD and seeking resources to better control CKD as well as significant moderate positive correlations between these SM activities and their SE counterparts (Table11). This is a valuable outcome as it suggests that a partnership can be created. This is compatible with the self-care nature that structured education should support and also the partnership with HCP's that the NHS is keen to establish (NICE, 2003; DoH, 2010).

The participants also identify the need for greater awareness among HCP about long term conditions (LTC's) in order to support individuals to manage and combine care to aid care plans and priorities of different conditions. This is an area where HCP may have to take an extra element of responsibility to aid self-care, which may involve learning of other health concerns and how to structure care plans which combine other potentially unrelated conditions.

> *Sometimes you go to one clinic and they say one thing and you go to another clinic and they say something entirely different and you think to yourself well what am I doing wrong, and then of course, when you ask them a question they*

say oh right, and you tell them I've been to this clinic and they said this, they say well stick to that"

The implication of a growing population with multiple comorbidities (Barrett et al., 2012) is an area that the NHS acknowledges as requiring newer structures for service provision (DoH, 2010). May, Montori, & Mair, (2009) highlight that multiple LTC can result in individuals managing multiple medications, self-monitoring, and consideration of diet and lifestyle priorities combined with time and effort to attend multiple separate clinical appointments. Lack of consideration and appropriate patient centred care plans can result in medication regimes that individuals cannot appropriately manage, potential adverse drug interactions or side effects and non-adherence by the individual as a result (May et al., 2009).

This current intervention combined two chronic conditions, however it is acknowledged that other LTCs can also be present and this will affect individual's priorities and management strategies which is an important consideration for all HCPs.

5.3.3.2 Social support

A value of the QIs was in highlighting that social support and in particular family support, has a substantial impact on participants sense of SE and SM activities, with positive and negative implications depending on the nature of the support available. Participants who had the support of family members identified the positivity this had on their ability to make changes, through encouragement, motivation and in one instance the completive nature of maintaining changes

"With the help of my wife, I know how to look after my diabetes."

In contrast to this barriers to changes were also demonstrated through lack of support. These participants suggest that they are challenged to make the necessary behavioural changes due to the negative implications of those close to them, for example,

> *"I'm not actively thinking about it [making behaviour change]. If my wife was more actively involved, and that sounds like a cop out really, but there would be, I would feel that would be a real step forward."*

The quantitative results show no change in SE or SM skills in relation to seeking support or discussing frustrations or worries with family or friends. Further to this a moderate correlation was found between these variables (Table 12). These findings combined would suggests that those who feel they can discuss feelings or problems with others are those that do so; while those who do not feel they can discuss issues with their social network, do not feel empowered to do so as a result of the intervention and therefore remain unable to engage with others. The qualitative results would suggest that this does have an impact on participant's actions and participants suggest beneficial effects of social support for SM. This is a learning point for the current education intervention, as the module did not incorporate significant consideration of gaining support from family members or actively encouraging engagement from those who would affect management skills, negatively or positively. The invitation to bring a second person to the group was offered and the encouragement of making practical changes suggested involving family members for support purposes. Potentially the intervention needs to extend further in this area to aid participant SE towards discussing support from their social network and methods of encouraging positive support. Overall, this would highlight the need not only for the individual with DKD to be involved in structured education but also their immediate support network, given the influence they hold.

A systematic review of the literature in this area suggests that social support does affect SM practices and diabetes outcomes (van Dam, van der Horst, Knoops, Ryckman, Crebolder, & van den Borne, 2005). The review found that group consultations incorporating a three monthly group diabetes review and education with the physician did improve HbA1c and lifestyle practices (Tranton et al., 2001). Peer support groups incorporating diabetes education and continued social support for 18 months delivered improved knowledge and QoL and less stress. This was in addition to the improvements seen in a diabetes education alone intervention which demonstrated improved diabetes control, less stress and greater involvement of family (Gilden, Hendryx, Clar, Casia, & Singh, 1992). The one study identified to access the role of family support specifically was measured in a weight loss and lifestyle behaviour intervention aimed at identifying the role of spouse involvement in an obese T2DM population over 18 months (Wing, Marcus, Epstein, & Jawad, 1991). The study identified that for male participants better outcomes in weight loss were achieved without the support of spouses, whereas the opposite was true for females (Wing et al., 1991).

It is evident that all of these interventions are much more intensive than the current research; however of interest is that the authors conclude that mechanisms from the individual studies could provide effective strategies for improved support (van Dam et al., 2005). This could include effective diabetes group education, better organisational deliver of care and enhanced interactions between HCP's and people with diabetes. Overall it is acknowledged that greater research is warranted in the area and that support may need to be adaptable to the individuals' needs and what they need or desire from support structures, considerate of family, peer or professional support (van Dam et al., 2005).

The current study suggests that family support is important to this cohort and it is acknowledged that this may be a barrier to change or an effective enhancement of self-

care depending on whether there is negative or positive support available. It is an important consideration which should be utilised in consultations with individuals in order to identify a self-care plan which is considerate of the implication of the support or lack thereof, in each individual case.

5.3.3 Correlation with knowledge

Similar to the present study, multiple other sources have reported the benefits of education in improving knowledge (Deakin et al., 2005; Knight et al., 2006; Mason et al., 2008; Stead et al., 2005). This has value as without knowledge, people have no reason to change. In theory, individuals require increased knowledge to improve management of their condition, however as stated earlier improved knowledge through diabetes education has not been shown to result in improved biomedical outcome measures unless the actual principles of education are implemented and maintained by the individual (Gomersall et al., 2011). This lack of improvement in HbA1c is potentially due to a lack of implementation of new knowledge in the form of necessary behaviour changes. It is proposed that the areas of knowledge, SM and SE are all required in order to improve HbA1c (Al-Khawaldeh et al., 2012). Stead et al. (2005) demonstrated improvements in knowledge, and limited improvements in SE related to exercise and blood glucose monitoring and SM behaviours related to diet, exercise, blood glucose monitoring and foot care. This was accompanied by a trend towards improvements in HbA1c at three months post intervention. The authors do emphasis that the study population did not have particularly high HbA1c measure at the onset of the study (67± 51- 84 14 mmol/mol; 8.29 ± 1.5%) therefore making it more difficult to show improvement.

Other research shows there was a no association between knowledge and receiving the diabetes healthcare essentials HbA1c, cholesterol and urine micoalbuminuria screening or foot examinations (Persell et al., 2004). The authors suggest that people who access

education are assume to have accessed the diabetes healthcare essentials, by virtue of being more knowledge and potentially that those providing the education are assumed to ensure the provision of these measures (Persell et al., 2004).

Many studies have identified improvements in SM activities in relation to diabetes management, yet this has not been reflected in long term improvements in biomedical outcomes (Al-Khawaldeh et al., 2012; Davies et al., 2008; Stead et al., 2005) and perhaps Persell et al. (2004) has highlighted a gap in current education provision that needs to be addressed in order for self-care activities to translate into biomedical outcomes that has the potential to change long term outcomes. Given the chronic progressive nature of diabetes this may hold understandable benefits; the changing dynamic of diabetes often necessitates continuous monitoring, hence the fifteen healthcare essentials (Diabetes UK, 2011) and adjustment of management practice in order to identify when current management no longer suffices, to aid achievement of optimal control.

Clinically, HbA1c is central to optimal diabetes management given its significance in long term management and risk management (DCCT, 1993) however it has been found that individual understanding of this biomedical measure in poor (Beard et al., 2009). As discussed earlier understanding of biomedical information, particularly HbA1c may play an important role in improving diabetes control (Beard et al., 2009), however consideration of education, communication with HCP, social support and potentially self-monitoring of blood glucose were also identified as important (Heisler et al., 2005; Skeie, et al., 2001; van Dam et al., 2005). This necessitates the need for multiple components to optimise SM and this is acknowledged as major implication in diabetes (McNabb, 1997). As a result, it is suggested that patients are non-adherent to care plans, however it should be acknowledge that the multi-nature approach to diabetes management may mean adherence in certain, yet not all SM activities. A recognition of the changeable nature of

diabetes, both in relation to daily activities and long term management plans needs to be expected and care plans should be generated in partnership between patients and HCP, with an emphasis on collaboration to strategize for this (McNab, 1997).

5.3.4 The need for continued support

It is worth considering that only 53.8% of participants reported receiving prior diabetes education and for a large proportion 42.9%) this education was over five years ago (Table 4). Potentially a proportion of the 30.8% who denied previous structured diabetes education may have actually received impromptu education, for example information received from clinic appointments. This is suggested given the qualitative feedback suggests that a level of knowledge was present prior to the education session and that many messages were reinforced.

This population have had DKD for a substantial period of time and yet benefits are demonstrated from the intervention, this suggests that repeated exposed to education has beneficial effects. Consideration of this, alongside the quantitative outcomes related to knowledge, further emphasis for the need for continued and ongoing educational support.

An Improvement in knowledge as a result of the education was demonstrated and this improvement is retained to different degrees at week twelve. As discussed previously, the peak of knowledge improvement is immediately post intervention, with retention reducing by twelve weeks post intervention. At twelve week, 62.5% of results are higher than at baseline but not as high as they had been immediate post-intervention. This shows that as time from intervention progresses, knowledge is reduced however remains higher than baseline in the majority of cases. This is a factor supported by other similar research

(Stead et al., 2005) and highlights the value of the need for access to regular DSE as encouraged by national guidelines (NICE, 2003),

NICE (2003) emphasis the need for education on an ongoing basis based on individual need and considerate of changes over time. While quality standard 6 of NICE (2011) in relation to diabetes education identified the need for access to DSE at diagnosed and on an annual basis. The current education would be suitable for those who develop DKD and would allow for more tailored education to individual need, while also being considerate of changes over time. DSE is deemed by NICE (2003) as being cost effective given the impact it can have on diabetes control, QoL and long term outcomes.

It is proposed that this standalone module was sufficient to provide the information sufficient to meet the needs of the population, demonstrating positive outcomes in many areas, without asking for greater commitment such as a course of sessions delivered over a number of days or weeks. Although HCP can see the worth in more elaborate and more intensive input, this may not be compatible with certain patients and results in reduced uptake and greater attrition, this has been demonstrated in courses targeting similar populations with a greater time commitment over multiple visits (Steed et al., 2005).

5.4 Strengths

The dual methodology of the study allows quantitative analysis of standardising questionnaires to investigate changes over time combined with QIs to add greater depth and robustness to the findings and give a fuller understanding of the outcomes. The qualitative element by nature of the semi-structured QIs allow for factors that affect the participants, but not considered by the researchers to be identified and analysed in the research. This offers an extra dimension to the study in terms of the multifactorial

approach that is DKD self-care and is considerate of NICE guidelines to incorporate this type of research to aid the identification of factors important to patients (NICE, 2003).

5.5 Limitations

5.5.1 Sample size

As previous acknowledge the recruitment numbers and time scales was a limiting factor for the study, considerate of the resources available for this Master's degree project. A criticism of the sample size is that it may be under powered to detect significant change. However the design of the study in using the mixed methodology approach does add extra merit to the results.

5.5.2 Questionnaires

There are also limitations of the questionnaires used; both the CKD-SE and CKD-SM are new measurement tools which have not been used in repeated measure studies previously. Considering the participants rated on the higher range in the majority of scores at baseline, the tools then became limited in their ability to convey whether positive changes resulted from the intervention. A "ceiling effect" may have been created due to the tools used; this is, the initially score is so good that improvements are hard to detect. Potentially using scales which were able to convey positive, negative or lack of change as a result of the intervention would have been more enlightening. Once such questionnaire for the assessment of SM behaviours is the Revised Summary of Self-Care Diabetes Activities Measure (Toobert, Hampson & Glasgow, 2000) which has been utilised previously in education intervention in people with T2DM (Steed et al., 2005; Al-Khawaldeh et al., 2012). This took has been shown to have acceptable internal consistency, test-retest correlation and no issues with ceiling effect reported in other studies.

Similarly, the Diabetes Multidimensional diabetes scale (Talbot, Nouwen, Gingras, Gosselin, & Audet, 1997) could have had benefits over the CKD-SE questionnaire. It measures SE, diabetes and social support perceptions and behaviours of self-care. It has demonstrated good internal consistency in patients with T2DM and has been used in similar cohort without issues regarding ceiling effect (Steed et al., 2005).

The additional benefit of utilising these two questionnaires is that it gives the opportunity to compare to the current education to interventions which have used the same tools (Al-Khawaldeh et al., 2012; Steed et al., 2005). This may have allowed for more comparisons to be made between the various interventions.

The selection of the CKD-SM and CKD-SE questionnaire was to incorporate specific questionnaires linked to CKD in order to consider the CKD element of the condition. It is acknowledge by Mason et al. (2008) that there is a lack of CKD specific questionnaire and that the development and use of such questionnaires should be supported. However this should be considered alongside the fact that the CKD-SE tool was relative recent and did require further interventions to identify its ability to detect change over time allowing it to be used in the evaluation of interventions (Walker & Buchbinder, 2012). The use of it in this current study suggests that its use in detecting change may be limited. However, the benefit of using the current questionnaires is that the elements were deemed pertinent to the behaviours that were desirable outcomes from the intervention and they were allow further investigation through the QIs, given further strength to the study outcomes.

In the completion of the KiKS there is an increase in no responses at week 6 and the reason for this is unknown. Potentially it is the design of the study that reduced responses, week 6 was the only point where qualitative and quantitative elements coincided. Visit 1 incorporated baseline data collection, the education intervention and the post education

visit therefore carrying the greatest time and study burden, yet non-responses were much lower. Week 6 had the same strategy for questionnaire completion as baseline; however it could be speculated that the QIs carried a substantial participant burden that potentially reduced their desire to complete the additional questionnaires appropriately. Perhaps the manner of completing the questionnaires at home (week 12) was preferred over the completion at the study site (week 6) as it allowed greater compatibility with participant's needs, e.g. time and comfort.

5.5.3 Sample composition

A positive of this research project is that the lack of attrition of the study population over the intervention period, which reduced biases which could have occurred should certain participants have been lost to follow up. As acknowledged earlier Steed et al., (2005) showed in a similar study population that those who did not complete the study were those with a higher baseline HbA1c. This suggests that those who partake in research are potentially those who are more motivated to engage and see the benefit of the intervention. This leads to the proposal that in this current cohort, it may be those more willing to engage or who are already engaged with the SM advice who agreed to partake, and this is reflected in the biomedical achievements of this cohort as discussed earlier (Table 1).

As described previously, the study sample lacked ethnic diversity which reduces the generalisation of the study findings to the wider population.

The median duration of DKD in this population was 7 years (IQR 6-7 years), therefore this is not a new condition for this population. As discussed previously, research does suggest that those with greater knowledge are those who have had a longer duration of diabetes which is thought to be related to accumulation of information (Skeie, et al., 2001). Also Norris et al. (2012) identified that greater contact time with HCP's was associated with

better diabetes control. Both of these studies would support the possibility that longer duration and engagement with HCP's leads to better control, which may be reflected in the current cohort. These findings would suggest that the potential exist for a greater impact of this type of education at an earlier stage of diagnosis as individuals will have had less contact with HCP's.

5.5 Implications of the results

The study adds to research in DSE specifically for DKD and demonstrated the benefits a compact standalone module can have on patient outcomes.

Education is a well-accepted standard of DSE and this study supports the use of education in DKD. It is acknowledge that not all SM and SE variable showed improvements in the current population, however it is proposed that the changes demonstrated as a result of a two hour DSE intervention, were substantial enough to be clinically beneficial as part of routine clinical care.

The NHS is encouraged to make available group DSE on a regular basis and considerate of ongoing needs of the patients (NICE, 2003). Given the progressive nature and increased risk of CKD in people with diabetes (Hippisley-Cox &Coupland, 2010), offering tailored education allows for education to meet the changing needs of the population. This study demonstrated the positive outcomes of such intervention on patient self-care and emphasis that as time from education progresses so too does knowledge and SM, therefore access to education on a regular basis is supported.

Extending the outcomes of the research to clinical care, suggests the need for awareness of HCP of the importance of social support to aid patient self-management, and the negative implication of SM and lack of ability to implement SM care plans if such support is

not available . Partnership between HCP and patients is also of importance as the study demonstrates that sharing of information by HCPs can be lacking. However with appropriate education and sharing of information between patient and HCP, SE and SM improves, and previous research suggests this may aid overall control (Polonsky et al., 2005)

Future research

The current study population represent a well-controlled cohort, who were more likely to have the access to the diabetes healthcare essentials which could implicate a greater degree of input by HCP's and awareness of their condition (Health and Social Care Information Centre, 2014; Persell et al., 2010). It would be interesting to repeat this study in a population with a relatively recent diagnoses of DKD as a way of aiding management of the condition prior to the need for escalation to specialist secondary care service, given the major role of diet and lifestyle in the management of DKD in delaying the progression of DKD (Gaede et al., 2003) and also considerate that earlier interventions are proposed to aid management of DKD in the long term (Mason et al., 2008). This is considerate of the manner in which the NHS is directing current service provision by facilitating greater ownership of LTCs by patients in primary care practice (Coulter, Roberts, & Dixon, 2013).

Secondly, it would be useful to explore the potentially reasons for the lack of correlation in the current study further in order to identify reasons for a lack of correlation between SE and SM. In the studies discussed, each uses different self-completed questionnaire to identify levels of SM and SE, and this potentially affect the outcomes. The questionnaires used in the present study may be a limitation to identifying correlations as both measures had outcome values on the higher side of the scale and a ceiling effect of both

questionnaires is proposed as a result of high values at baseline. This limitation is considered further in the limitation section.

Conclusion

The present study shows a benefit in improving knowledge related to CKD, alongside certain SE and SM behaviours important to DKD management. The study cohort was a relatively well controlled group represented by a median HbA1c within treatment target and high levels of SE and SM at baseline.

However, notwithstanding this, the intervention successfully improved aspects of DKD important to effective SM. Previous research identified the role of these SM practices in risk reduction and delayed progression of DKD (Gaede et al., 2003; Mason et al., 2008). SM improvements were demonstrated in dietary adjustments, seeking support, and asking about biomedical results. Previous research has demonstrated positive effects on diabetes control, hypertension and dyslipidaemias as a result of improvements in these factors (Delanhanty & Halford, 1993; Gaede et al., 2003; Polonsky et al., 2005; van Dam et al., 2005).

Similar to other research in the area of DSE no correlation was found between knowledge and SM (Gomersall et al., 2011). Therefore this study adds to the evidence that increased knowledge does not correlate in improvements in SM and as a result education providers need to ensure education is in the format to support SE and SE, rather than purely knowledge focused.

Qualitative findings emphasis the practical daily SM participants have instigated or improved upon as a results of the education and strengthens the likelihood that improvement are being made in SM behaviours. The QIs identify the need for positive social support to enhance SE and progress SM. They emphasise that a lack of support impedes SM which should be an important consideration of SDE. Potentially, initial SM care plan need to Identify social support, develop engagement of family members and work to resolve negative social support if evident.

To conclude a DSE disease-specific module for DKD has positive implication for patient care, in terms of SM, SE, knowledge and overall patient experience. The module is consistent with national guidelines to provide appropriate, ongoing education in a manner compatible with engaging participants in self-care, which is an important endeavour of current NHS strategies (Coulter et al., 2013; NICE, 2003).

Further research into the effectiveness in newly diagnosed DKD is warranted as evidence suggest the modules may have the potential to have a greater impact in primary care, where newer diagnosis and an earlier emphasis on self-care may reduce the disease progression and delay the use of specialist secondary care services (Mason et al., 2008; Norris et al., 2012)

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Appendix 1 Ethical Approval

NHS
Health Research Authority
National Research Ethics Service

NRES Committee North West –Preston
3rd Floor
Barlow House
4 Minshull Street
Manchester
M1 3DZ

Telephone: 0161 625 7434

28 February 2013

Susan Gallagher
Countess of Chester NHS Foundation Trust
Liverpool Road
Chester
CH2 1UL

Dear Susan

Study title: **A modular approach to diabetes structured group education: The effects of Diabetes Essentials: Kidneys on patient knowledge, self-efficacy, self-care behaviour and patient experience in diabetic kidney disease**
REC reference: **13/NW/0167**
Protocol number: **Non applicable**
IRAS project ID: **119395**

Thank you for your email of 27 February 2013. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 26 February 2013

Documents received

The documents received were as follows:

Document	*Version*	*Date*
Participant Consent Form: Qualitative Research	2	27 February 2013
Participant Information Sheet	2	27 February 2013

Approved documents

The final list of approved documentation for the study is therefore as follows:

Document	*Version*	*Date*
Evidence of insurance or indemnity		09 July 2012
Interview Schedules/Topic Guides	1.0	14 February 2013
Investigator CV	Duane Mellor	18 January 2013
Investigator CV	Susan Gallagher	14 February 2013

Appendix 1 Ethical Approval (continued)

Investigator CV	Franklin Joseph	14 February 2013
Investigator CV	Dr Jan Hopkins	
Letter from Statistician		14 February 2013
Letter of invitation to participant	1.0	14 February 2013
Other: Letter from Funder		
Other: Visit 1 Data Collection Form	1.0	14 February 2013
Participant Consent Form: Patient	1.0	14 February 2013
Participant Consent Form: Qualitative Research	2	27 February 2013
Participant Information Sheet	2	27 February 2013
Protocol	1.0	14 February 2013
Questionnaire: Baseline Questionnaire	1.0	14 February 2013
Questionnaire: CKD Self-Management Questionnaire	1.0	14 February 2013
Questionnaire: CKD Self-efficacy Questionnaire	1.0	14 February 2013
Questionnaire: Kidney Disease Knowledge Survey	1.0	14 February 2013
REC application	3.4	18 February 2013
Referees or other scientific critique report	Letter	14 February 2013
Summary/Synopsis	1.0	14 February 2013

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

13/NW/0167 **Please quote this number on all correspondence**

Anna Bannister
Assistant Committee Co-ordinator

E-mail: nrescommittee.northwest-preston@nhs.net

Copy to: *Mr Duane Mellor*
Sheila Williams, Countess of Chester NHS Foundation Trust

Appendix 2: Research & Innovation approval letter

Countess of Chester Hospital NHS
NHS Foundation Trust

The Countess of Chester Health Park
Liverpool Road
Chester
CH2 1UL

Research & Innovation Department
Tel: 01244 365532
Email: sheila.williams4@nhs.net

26 February 2013

CONFIDENTIAL

Ms Susan Gallagher
Countess of Chester NHS Foundation Trust
Liverpool Road
Chester
CH2 1UL

Dear Ms Gallagher

Study Title: **A modular approach to diabetes structured group education: The effects of Diabetes Essentials: Kidneys on patient knowledge, self-efficacy, self-care behaviour and patient experience in diabetic kidney disease.**
REC Ref: **13/NW/0167**
Protocol: **Version 1 (14/01/13)**
R&D Ref: **Stud069/13**

The Research & Innovation Department is pleased to approve this project, together with the indemnity and financial assessments and hopes that it proves to be interesting and rewarding.

You are reminded that although this project has been approved by the Trust, all research must also have appropriate ethical committee approval **before** it is undertaken.

As part of research governance, the Research & Innovation Department is required to monitor the progress and outcome of research within the Trust. Therefore, whilst this project continues Mrs Sheila Williams, Research Manager will be in contact annually to request a brief update and the Research & Innovation Department would be grateful for a summary on completion of the project, (if available, a copy of any publication or an abstract of a presentation relating to this study would suffice).

Conditions of approval

In addition, please note you must inform us if your project deviates in any way from the original proposal/documentation you have submitted. Your approval is limited to the dates stated on the research application form and that you are obliged to notify the Research & Innovation Department of any adverse events that arise during the course of the project. May I remind you that you are obliged to adhere to the Research Governance Framework for Health and Social Care (2005). If it is found that this is not the case, this may result in the suspension of your project until changes have been agreed with the Trust, or your research may be terminated pending an enquiry.

Appendix 2: Research & Innovation Approval letter (continued)

Permissions

This letter authorises you in principle to undertake research within the Trust. However, it is your responsibility to ensure that individuals appropriate to your work have no objections to your studies. This department accepts no liability for non co-operation of staffs or patients.

Auditing

I would strongly urge you to maintain an accurate and up to date site file for your documentation, as the Trust randomly audits projects to assess compliance with the relevant frameworks and legislation. If your study is chosen, you will be notified in writing not less than two weeks prior to the required submission date of documentation.

Reporting

In the interest of ensuring the Trust receives maximum benefit from co-operating with research projects such as your own, the Trust places great importance on disseminating findings and conclusions. Therefore we would welcome a short summary of the findings of this project, once completed, along with any formal publications resulting from this work.

I would like to take this opportunity to wish you well with your project. If you have any questions or I can be of any further assistance to you, please do not hesitate to contact me.

Mrs Sheila Williams
Research & Innovation Manager

Appendix 3 Consent Form (Quantitative Research)

Countess of Chester Hospital NHS
NHS Foundation Trust

University of Chester

PARTICIPANT CONSENT FORM

Title of Project: **Diabetes Essentials Kidneys: Does education improve outcomes**
A modular approach to Diabetes structured group education: The effects of Diabetes Essentials: Kidneys on patient knowledge, self-efficacy, self-care behaviour and patient experience.

Name of Researcher: Susan Gallagher

Please INITIAL box

1. I have read and understand the patient information sheet for the above study. I hav had the opportunity to consider the information, to ask questions and to have these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the hospital, and from individuals within hospitals Research & Development office. I give permission for these individuals to have access to my records. ☐
4. I understand that my data will be held on a computer at the hospital. I give my permission for this data to be held on computer by this party. ☐
5. I agree to take part in the above study. ☐

_____	_____	_____
Name of Participant		Date Signature
_____	_____	_____
Name of Person taking consent	Date	Signature

When completed; 1 for participant (copy); 1 for researcher (original); 1 to be kept with hospital notes (copy)

Appendix 4 Consent Form (Qualitative Research)

Countess of Chester Hospital NHS
NHS Foundation Trust

University of Chester

PARTICIPANT CONSENT FORM: PART 2

Title of Project: Diabetes Essentials Kidneys: Does education improve outcomes

A modular approach to Diabetes structured group education: The effects of Diabetes Essentials: Kidneys on patient knowledge, self-efficacy, self-care behaviour and patient experience.

		Yes	No
1	I confirm that I have read and understood the information sheet for the above study. I have had the opportunity to consider the information, ask questions and where necessary, have had these answered satisfactorily.		
2	I **am willing** to participate in an interview		
3	I **am willing** to have the interview recorded.		
4	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason.		
5	I understand that my responses will be anonymised and my identity will not be revealed during the study or in any reports or publications.		
6	I understand that my direct quotes may be used in reports or publications however responses will be anonymised and no identifiable information will be used		
7	I understand that the researchers will hold all information and data collected in a secure and confidential manner.		
8	I understand that the data collected during the study may be looked at by individuals from regulatory authorities or from the NHS Trust where it is relevant to my taking part in this research. I give permission for these individuals to have access to this information.		

_____ _____ _____
Name of Participant Date Signature

_____ _____ _____
Name of Researcher Date Signature

When completed; 1 for participant (copy); 1 for researcher (original); 1 to be kept with hospital notes (copy)

Appendix 5 Participant invite letter

Countess of Chester Hospital NHS Foundation Trust

University of Chester

Diabetes Unit
Countess of Chester Hospital NHS Foundation Trust
Countess of Chester Hospital Health Park,
Liverpool Road
Chester
CH1 2UL

Date

No ,
X Street
Area
Town
Post Code

Dear X

Research Study

Diabetes Essentials Kidneys: Does education improve outcomes?

The Countess of Chester Hospital and the University of Chester are working together to carry out a research study and are writing to ask if you would be willing to take part.

The study is investigating the impact the group session **Diabetes Essentials: Kidney** has on the way people with diabetes manage their condition. It is hoped that by attending the group session people with diabetes and kidney problems will increase their knowledge of the condition, be in a better position to manage their condition themselves and potentially reduce the anxiety associated with living with this complex condition.

Why have I been asked?
You have been chosen because you have diabetes and your recent blood results show that you have kidney impairment. You are one of a number of people from across Western Cheshire Primary Care Trust that we are asking to help.

What would I have to do?

If you agree to take part, you will be asked some questions about your diabetes and how you manage it. You will also be asked to complete questionnaires, attend the education session (Diabetes Essentials: Kidneys) and have a discussion with a researcher about the affect the education session may have had on you.

It would involve two visits to the Countess of Chester Hospital. The first visit involves completing questionnaires and attending the group education module "Diabetes Essentials: Kidneys" (**Please note you will have already have received an appointment letter for this education session**). The second visit (6 weeks later) involves an individual discussion with a researcher to tell us more about your overall experience of the education session and how it may have affected you. A third contact (12 weeks after the initial education session) involves completing questionnaires and will be arranged to suit your preference (a telephone call/by post /individual face to face contact).

The researchers will cover reasonable travel expenses for all your visits.

How do I reply?
If you think you might want to know more, please register your interest **within the next two weeks** in one of these ways:

1. You could complete the reply-slip attached and return it to the research dietitian, Susan Gallagher at the above address. A researcher will telephone you to discuss the study.

2. You can telephone the Diabetes Unit at the Countess of Chester Hospital on to discuss the research further with the research dietitian.

If you are interested in taking part the researchers will give you more details about the study. By contacting us you will not be under any obligation to take part, and you will be free to change your mind at any time.

If you have any questions please contact Susan Gallagher, the research dietitian, on

The researchers look forward to hearing from you.

Yours sincerely,

Susan Gallagher
Diabetes Research Dietitian

- -- -- - - - - - - - - - - - - - -

Reply-slip

I am interested in knowing more about the research involving Diabetes Essentials: Kidneys looking at education for people with diabetes and kidney problems

Name:

Date of Birth:

Please contact me on this telephone number …………………………………

Or this telephone number…………………………………………………...

Between the times of………………………………………………………

Appendix 6 Participant information sheet

Countess of Chester Hospital NHS Foundation Trust

University of Chester

Version 2

PATIENT INFORMATION SHEET

Diabetes Essentials Kidneys: Does education improve outcomes?

A modular approach to Diabetes structured group education: The effects of Diabetes Essentials: Kidneys on patient knowledge, self-efficacy, self-care behaviour and patient experience.

You are being invited to take part in a research study. Before you make a decision, you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. One of the diabetes research team can go through the information sheet with you and answer any questions you may have. Please feel free to talk to your friends and family about the study. Ask us if there is anything that is not clear or if you would like any more information. Take time to decide whether or not you wish to take part in the study.

What is the purpose of the study?

All people with diabetes should have access to structured education as part of their routine care. The Countess of Chester Hospital NHS Foundation Trust offers diabetes education in the form of a once-off session known as 'Diabetes Essentials'. However diabetes is a complex condition and can have numerous health effects on an individual. Diabetes can affect your kidneys and cause kidney disease (known as diabetic kidney disease or diabetic nephropathy).

As each complication of diabetes has different effects and management needs, the Diabetes Unit at the Countess of Chester Hospital has developed education modules for specific complications. This includes an education session specific to diabetes and kidney disease known as Diabetes Essentials: Kidneys.

The education session will provide participants with information about the condition as well as information on the dietary, lifestyle and medical management of the disorder.

The purpose of this study is to evaluate if this education (Diabetes Essentials: Kidneys) can improve knowledge, self-management and your confidence in managing your condition.

Why have I been chosen?

You are due to attend the group education session 'Diabetes Essentials: Kidneys' because you have diabetes and your most recent blood results indicates that you have kidney impairment. We are asking you to take part in this research study because you are due to attend this education session.

Do I have to take part?

No. It is up to you to decide whether to take part or not. Participation in the study is voluntary.

Regardless of whether or not you take part in this research project, you are invited to attend the group education session Diabetes Essentials: Kidneys.

We will describe the study to you and go through this information sheet. If you are interested in taking part we will then ask you to sign a consent form to show you have agreed to take part in the study. You will receive a copy of this information sheet and the signed consent form.

You are free to withdraw from the study at any time, without giving a reason. Choosing to withdraw from the study will not affect the standard of your routine care.

What will happen to me if I take part?

If you decide to take part, you will be given this information sheet to keep and asked to sign the consent form. The study will last for three months and during this time

you will be asked to attend two appointments at the hospital and to be available for one other appointment, which can be carried out as a telephone, postal or individual appointment depending on your preference.

Contact 1

You can complete and return the reply slip which is attached to the bottom of your invite letter, giving a suitable date, time and contact number on which the researcher can contact you to discuss the research further. Alternatively you can call the researcher to discuss the proposed research further on 01244 363786

If we do not hear back from you within two weeks, we will make contact with you via telephone to ask if you wish to participate in the research.

Following this, if you are interested you will be provided with an appointment time, immediately prior to your scheduled education session in order to complete research questionnaires.

Contact 2

This contact will take place at the Diabetes Unit, Countess of Chester Hospital NHS Foundation Trust. At contact 2 you will have the opportunity to ask any questions you may have regarding the research. If you are happy to continue you will be asked to sign a consent form to consent to participate in the study.
At this visit we will also gather some information about you and your diabetes and also ask you to complete questionnaires.

The education session 'Diabetes Essentials: Kidneys' will also be delivered at this visit. This is an informal group session with approximately nine other people with the same condition as you. This session will be delivered by a diabetes specialist nurse.

Your medical records will be looked at and if you have not had your bloods and urine checked in the three months previous to this visit, you will be asked to provide a urine and blood sample. Also if your weight and blood pressure have not been recorded in the previously three months, this will also be measured at Contact 2. If adult height is available it will be accepted regardless of whether it was in the previous three months. It will be measured at contact 2 if it is not available in medical records.

This whole visit (including the education session) will last approximately three and a half hours.

Contact 3

This contact will take place at the Diabetes Unit, Countess of Chester Hospital NHS Foundation Trust.
It will involve an individual discussion with a trained researcher from Liverpool John Moores University. It will involve questions regarding your overall experience of the education session and how it may have affected you. For the purposes of the study it will be voice recorded.

The contact will also involve completion of one written questionnaire. The contact will be pre-arranged at a date and time convenient to you and the researcher and will aim to coincide with other appointments you may have at the hospital if possible. It is expected to take approximately 30 to 60 minutes.

Contact 4

This will be the final contact of the study. This can be arranged by means to suit your preference. It can be done as a telephone consultation with the researcher; completing written questionnaires and returning them by post; or as an individual face to face consultation with the researcher at the Diabetes Unit, Countess of Chester Hospital NHS Foundation Trust.

You will be asked to complete three questionnaires in relation to your diabetes. It is expected to take approximately 45 minutes.

What are the possible disadvantages and risks of taking part?

There are no identifiable risks in taking part in this study.

The only disadvantage is the additional time it will involve and the burden this would cause for you. The researcher will be as flexible as possible in arranging scheduled contacts and appointment time convenient to you.

The cost of travelling to and from the hospital for all of the visits and if applicable, parking fees, will be reimbursed to you therefore removing any financial burden of participating.

What are the possible benefits of taking part?

By taking part you will be contributing to the development of the diabetes service at the Countess of Chester Hospital NHS Foundation Trust which will hopefully help people in a similar position to you.

What if something goes wrong?

In the unlikely event that something goes wrong as a result of taking part in the study, the Countess of Chester Hospital NHS Foundation Trust provides insurance cover and you would retain the same rights of care as any other patient treated in the National Health Service.

If you have any concerns or wish to complain about any aspect of the way you have been approached or treated during the course of this study, please contact Sheila Williams, Research Manager Countess of Chester Hospital NHS Foundation Trust, Countess of Chester Health Park, Liverpool Road, Chester, CH2 1UL Telephone: 01244 365532

Any concerns or complaints can also be submitted to the Countess of Chester Hospital NHS Foundation Trust Patient Advice and Liaison Service (PALS) department by contacting 0800 195 1241, alternatively email PALS on cochpals@nhs.net or write to PALS Manager, PALS, Countess of Chester Hospital Foundation Trust, Liverpool Road, Chester CH2 1UL.

Will my taking part in the study be kept confidential?

Yes, all information gathered during the research study will be kept confidential. Only people directly involved in the research will have access to details of your participation. The lead researcher will have responsibility for ensuring that all information is kept in a secure manner. Your medical records will not leave the hospital. For the purposes of analysing and presenting the final results, all information will be anonymised so participants will not be identifiable.
A trained researcher from Liverpool John Moore University will be involved in the project for contact 3. They will have a duty of confidentiality to you and will ensure

strict confidentiality. Only minimal information (and no specific clinical information) will be passed to this researcher. This will follow an agreement between the University and the Countess of Chester Hospital NHS Foundation Trust.

What will happen to the results of the research study?

The results will be used to help evaluate and develop the education provided by the Diabetes Unit at the Countess of Chester Hospital NHS Foundation Trust. They will also be used as part of a master level student research project and may be presented at meetings or published in a journal with interest in diabetes.

Who is organising and funding the research?

The Diabetes Research Fund at the Countess of Chester Hospital NHS Foundation Trust is funding this current research.

Who may I contact for further information?

If you have questions or concerns regarding participation in the research, you are encouraged to speak to you GP who can give you an independent opinion on the research.

If you have any question or would like to discuss this research further please contact Susan Gallagher (lead researcher) at the Diabetes Unit, Countess of Chester Hospital NHS Foundation Trust on or by emailing

Thank you for taking the time to read this information

Appendix 7 Participant questionnaire permission: KiKS

Dear Susan,
Thank you for your interest in the KiKS. You are welcome to use it and we only ask that you reference the AJKD publication if you report your findings.

As for the scoring we do not weight any of the items, thus omitting 3 that you do not think may be relevant in your sample will be unlikely to significantly modify the properties of the assessment. Just rescore the remaining items as the % correct.

Best wishes,
Kerri

Kerri Cavanaugh, MD MHS
Assistant Professor of Medicine
Vanderbilt University Medical Center
Division of Nephrology
Center for Health Services Research
1161 21st Ave South
S-3223 MCN
Nashville, TN 37232-2372

From: Gallagher Susan (COUNTESS OF CHESTER HOSPITAL NHS FOUNDATION TRUST)
Sent: Friday, November 30, 2012 9:26 AM
To: Cavanaugh, Kerri
Subject: Kidney Knowledge Survey (KiKs) Request

Dear Ms Cavanaugh,

I am emailing in relation to your research into a knowledge survey for patients with CKD. I am undertaking my Master degree dissertation in the area of diabetic nephropathy education and having recently read the paper on 'Development and results of a kidney disease knowledge survey given to patients with CKD'. I feel that KiKS would be suitable to use to determine knowledge in my proposed patient group. Would I require permissions or a license to use this particular survey for my research?

Also there are three questions that I feel I would not expect this particular group to know the answer to. Would the use of the survey allow me to omit these questions?

Kind Regards
Susan

Appendix 8 Participant questionnaire permission: CKD-SM & CKD-SE

Dear Susan,

I sincerely apologize for delaying my reply.

Attached please find the CKD-SE in which there presents both English and Chinese.

Regarding the CKD-SM, the completed sentence of each item in English have not done.

Best wishes,

Chiu-Chu

----------On Tue, 27 Nov 2012 11:04:39 +0000, Gallagher Susan (COUNTESS OF CHESTER HOSPITAL NHS FOUNDATION TRUST) wrote

Good Afternoon,

I have today come across your paper 'Psychometric evaluation of a new instrument to measure disease self-management of the early stage chronic kidney disease patients'.

Similar to my email correspondence yesterday regarding the CKD-SE scale- I wonder is it possible that I may use this questionnaire in my Master degree dissertation? Is there any permissions/licences I am required to get in order to use it? And is there a 'patient friend' version of the scale for use?

Kind Regards
Susan

Susan Gallagher
Dietitian

Countess of Chester Hospital NHS Foundation Trust
Countess of Chester Health Park
Liverpool Road
Chester
Cheshire
CH2 1UL

Appendix 9 Researcher-administered questionnaire

Countess of Chester Hospital NHS
NHS Foundation Trust

University of Chester

For Completion by the Researcher (from patient medical records)

Diabetes diagnosed (MM/YY)…….

Diagnosed with Diabetic Nephropathy (MM/YY)……..
(Assessed by date of first abnormal microalbuminuria as documented in medical records)

Medication and doses

Diabetes medications

_____

_____

_____

_____

Anti-hypertensive medications

_____

_____

_____

_____

Dyslipidaemia medications

_____

_____

_____

_____

Does the participant have other complication of diabetes?

- ☐ Retinopathy
- ☐ Neuropathy
- ☐ Cardiovascular disease
- ☐ Peripheral vascular disease

Biomedical Results

Glycated Haemoglobin (HbA1c)	_____ mmol/mol
Estimated Glomeular Filration Rate (eGFR)	_____ ml/min/1.73 m2
Miroalbuminuria (MCACR) (if applicable)	_____ mg/mmol
Proteinuria (Urine Prot/Cr) (if applicable)	_____ mg/mmol
Total Cholesterol	_____ mmol/L
HDL Cholesterol	_____ mmol/L
LDL Cholesterol	_____ mmol/L
Total/HDL ratio	_____
Triglycerides	_____ mmol/L
Blood Pressure	_____ mm Hg
Height	_____ m
Weight	_____ kg
Body Mass Index	_____ kg/m²

Questionnaire complete	**Complete**	**Not Complete**
Pre intervention knowledge questionnaire	☐	☐
Pre-intervention self-efficacy questionnaire	☐	☐
Pre-intervention self-management questionnaire	☐	☐
Post-intervention knowledge questionnaire	☐	☐
Post-intervention self-efficacy questionnaire	☐	☐

Patients preferred method of participating in qualitative research

- ☐ Face to Face appointment with research at COCH Diabetes Unit
- ☐ Postal questionnaires
- ☐ Telephone questionnaires

Appendix 10 Baseline data questionnaire

Countess of Chester Hospital NHS
NHS Foundation Trust

University of Chester

About You

Participant Number:

Gender Male ☐ Female ☐

Date of Birth _____/_____/_____

White

- ☐ British
- ☐ Irish
- ☐ Any other White background

Mixed

- ☐ White and Black Caribbean
- ☐ White and Black African
- ☐ White and Asian
- ☐ Any other mixed background

Asian or Asian British

- ☐ Indian
- ☐ Pakistani
- ☐ Bangladeshi
- ☐ Any other Asian background

Black or Black British

- ☐ Caribbean
- ☐ African
- ☐ Any other Black background

Other Ethnic Groups

- ☐ Chinese
- ☐ Any other ethnic group

Highest level of education:

☐ 1-4 O Levels, CSEs, GCSEs (any grade), Entry Level, Foundation Diploma

☐ NVQ Level 1, Foundation GNVQ, Basic Skills

☐ 5+ O Levels (passes), CSEs (grade 1), GCSEs (grades (A*-C), School Certificate, 1 A level, 2-3 AS levels, VCEs, Higher Diploma

☐ NVQ Level 2, Intermediate GNVQ, City and Guilds Craft, BTEC First/General Diploma, RSA Diploma

☐ Apprenticeship

☐ 2+ A levels/VCEs, 4+AS levels, Higher School Certificate, Progression/Advanced Diploma

☐ NVQ Level 3, Advanced GNVQ, City and Guilds Advanced Craft, ONC, OND, BTEC National, RSA Advanced Diploma

☐ Degree (for example BA, BSc), Higher degree (for example MA, PhD, PGCE)

☐ NVQ Level 4-5, HNC, HND, RSA Higher Diploma, BTEC Higher Level

☐ Professional qualifications (for example teaching, nursing, accountancy)

☐ Other vocational/work related qualifications

☐ Foreign qualifications

☐ No qualifications

Employment Status

- ☐ Working full time (35 + hours per week)
- ☐ Working part time
- ☐ Unemployed
- ☐ Retired/Disability
- ☐ Homemaker
- ☐ Student
- ☐ Other, specify……

About your Diabetes

Which type of Diabetes do you have? Type 1 ☐ Type 2 ☐

Diabetes Medication (Please tick all that currently apply to you)

☐ **No medication**, diet and lifestyle only

☐ **Tablets** (e.g. Metformin, Gliclazide, Pioglitazone, Sitagliptin)

☐ **Incretin Mimetic** (Exenatide (Byetta/Bydureon) or Liraglutide (Victoza))

☐ **Insulin**

Do you have any other complication of diabetes?

☐ Retinopathy (damage to eyes)

☐ Neuropathy (nerve damage)

☐ Cardiovascular disease (affecting the heart)

☐ Peripheral vascular disease (affecting the limbs usually the feet)

Previous Diabetes Education

Have you received diabetes education in the past?

Yes ☐ No ☐

If yes, which of the following bests describe the education you have received?
(Please tick all that apply to you)

☐ One to one education with a health professional e.g Doctor/Nurse/Dietitian

☐ Diabetes Essentials

☐ Other generally diabetes education session (e.g. X-PERT programme, DESMOND, or other education session)

☐ Carbohydrate counting and insulin dose adjustment education (e.g. DISC, DAFNE or other carbohydrate and insulin dose adjustment education sessions)

☐ Other education, please specify……

How long did this education last?

☐ Less than 15 minute

☐ 15-30 minutes

☐ 30-60 minutes

☐ 1-3 hours

☐ Multiple sessions over a number of days/weeks

How long ago did you have this education? (Where you have had more than one type of education please indicate the time since the most recent education)

☐ In the past six months

☐ Within the previous year

☐ 1-2 years ago

☐ 2-5 years ago

☐ Greater than 5 years ago

Appendix 11 Participant questionnaire: CKD-SM

Countess of Chester Hospital NHS
NHS Foundation Trust

University of Chester

Chronic Kidney Disease Self-Management Questionnaire

The following statements relate to **how you manage** your chronic kidney disease (CKD)

Please choose a number on a scale of 1 to 4 of how often you feel you do the task described in each question where:

1 = Never **2 = Rarely** **3 =Often** **4 = Always**

There is **no right or wrong answer**, just answer how you feel currently in relation to the statements.

Please answer each question (1 -29)

If you have any questions please ask

Read each statement and decide how often you do that activity where

1= Never 2= Rarely 3=Often 4 = Always

In relation to your kidney disease **how often do you….**

1. Pay attention to habits that may affect kidney function e.g. your medication; your salt intake; your diabetes control; your weight; your physical activity levels **1 2 3 4**
2. Adjust your food portions and choices when you are eating out, meeting friends or attending celebrations e.g. choosing low fat or low salt foods when possible; eating smaller portions of foods that are high in fat or salt; keeping to portion sizes that are appropriate for you **1 2 3 4**
3. Give up habits harmful to the kidneys e.g. regular intake of high salt, high fat foods, high alcohol intake, sedentary lifestyle **1 2 3 4**
4. How often do you think about giving up smoking? Non applicable **1 2 3 4**
5. How often have you attempted to give up smoking? Non applicable **1 2 3 4**

Read each statement and decide how often you do that activity where

1= Never 2= Rarely 3=Often 4 = Always

In relation to your kidney disease **how often do you….**

6. Adjust the things you do to look after your kidneys to fit different situation Examples of different situation include when on holiday, eating out or away from home or socialising with family/friends. Examples of things to adjust may include: when to take your medication; how to accommodate exercise; choose low fat or salt meals and snacks; eat a smaller portion size than is served; take suitable food with you; research options before you travel **1 2 3 4**
7. Choose food options to avoid harming your kidneys e.g. choose low salt foods; reduce the amount of foods high in simple sugars; choose low fat foods; choose healthy portion sizes **1 2 3 4**
8. Manage CKD (Chronic Kidney Disease) to stay healthy e.g. know your blood and urine results and take steps to improve results, if needed; take your medication as advised by your medical team; aim for or maintain a healthy weight; take regular exercise; make choices to keep to a healthy diet **1 2 3 4**

Read each statement and decide how often you do that activity where

1= Never 2= Rarely 3=Often 4 = Always

In relation to your kidney disease **how often do you….**

9. Fit the things you need to do to look after your kidneys into your daily life e.g. taking your medication as prescribed, reduce the amount of salt or saturated fat in your meals; improve your diabetes control; ensure you are regularly physically active; aim for or maintain a healthy weight **1 2 3 4**
10. Adjust your lifestyle to maintain kidneys in the best condition e.g. ensure time is available for regular physical activity; improve your diabetes control if necessary; change the foods you eat in order to choose low salt options; if you are overweight make attempts to lose weight **1 2 3 4**
11. Participate selectively or avoid certain social activities examples of social activities: going to the pub or other situations where drinking alcohol is anticipated; eating takeaways or eating out; functions/activities where snacking is expected e.g. cinema, parties; avoiding situations where smoking is anticipated **1 2 3 4**

Read each statement and decide how often you do that activity where **1= Never 2= Rarely 3=Often 4 = Always**

In relation to your kidney disease **how often do you….**

12. Change lifestyle to avoid worsening of kidney function
e.g. avoid smoking; avoid high salt foods; include exercise regularly; make changes to aim to keep to a healthy weight; ensuring advice on medication is followed

1 2 3 4

13. Actively seek information about kidney disease
e.g. information on: what kidney disease is, what you can do to help control it

1 2 3 4

14. Actively seek resources to better control CKD (Chronic Kidney Disease)
e.g. advice on how to reduce your salt intake or advice on how to reduce your fat intake or your overall eating habits in relation to kidney disease advice; seek guidance on how to improve your diabetes control; information on the medication you use

1 2 3 4

15. Use different ways to clarify questions about your treatment plan
e.g. talking to your GP, Diabetes Specialist Nurse or other members of your diabetes or kidney specialist team; getting information from patient information booklets, internet resources or attending patient meeting groups such as your local Diabetes UK group; talking to other people with the condition

1 2 3 4

Read each statement and decide how often you do that activity where

1= Never 2= Rarely 3=Often 4 = Always

In relation to your kidney disease **how often do you….**

16. Use different ways to solve problems
e.g. talking to your GP, nurse or other members of your medical team; asking for advice on issues that matter to you in relation to your diabetes or kidney disease; identifying problems that you may have and identify how you can make changes; asking family or friends for help with solving problems; looking for information or support groups to help solve problems

1 2 3 4

17. Find out reasons for signs and symptoms of CKD (Chronic Kidney Disease)
e.g. talking to your GP, Diabetes Specialist Nurse or other members of your diabetes or kidney specialist team; getting information from patient information booklets or internet sites

1 2 3 4

18. Think about reasons for your abnormal blood or urine results

1 2 3 4

19. Find out possible reasons for your High Blood Pressure result

1 2 3 4

Read each statement and decide how often you do that activity where

1= Never 2= Rarely 3=Often 4 = Always

In relation to your kidney disease **how often do you….**

20. Ask the meaning of your blood and urine test results **1 2 3 4**
21. Seek to understand your risk factors of CKD (Chronic Kidney Disease) e.g. your blood pressure, your diabetes control, etc. **1 2 3 4**
22. Share your experience with other patients **1 2 3 4**
23. Share feelings of helplessness or frustration with other patients **1 2 3 4**
24. Ask your family or friends for help when you feel helpless or frustrated **1 2 3 4**
25. Discuss questions or worries you have with family or friends **1 2 3 4**

Read each statement and decide how often you do that activity where

1= Never 2= Rarely 3=Often 4 = Always

In relation to your kidney disease **how often do you….**

26. Tell your family or friends about your CKD (Chronic Kidney Disease) treatment plan **1 2 3 4**
27. Follow health care professional's suggestion to adjust your dietary habits e.g. follow a low salt diet, reduce your intake of saturated fat or follow a low potassium diet if advised **1 2 3 4**
28. Follow health care professional's suggestion to control your weight **1 2 3 4**
29. Follow health care professional's suggestion to exercise **1 2 3 4**
30. Follow the dieticians' suggestion on choosing food **1 2 3 4**

Please place the finished questionnaire in the envelope provided

Appendix 12 Participant questionnaire: CKD-SE

Countess of Chester Hospital NHS
NHS Foundation Trust

University of Chester

Chronic Kidney Disease Self Efficacy questionnaire

The following statements relate to **how confidently you feel** about your management of

Chronic Kidney Disease CKD

Please choose a number on a scale of 1 to 10 of how confident you feel where

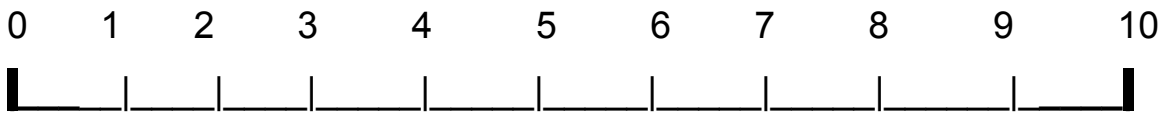
0 means not confident

and

10 means extremely confident

Circle a number on the scale for each question

0 = Not confident 10= Extremely Confident



There is no right or wrong answer, just answer honestly about how you feel.

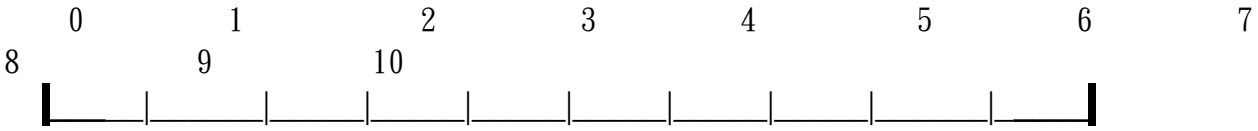
Please answer each question (1 – 25)

If you have any questions please ask

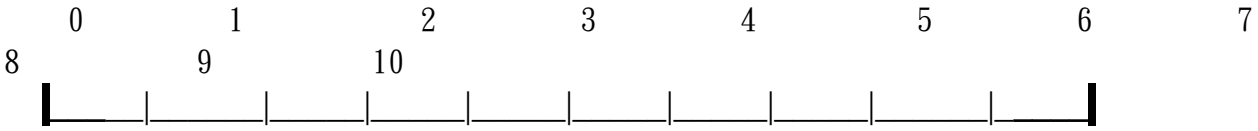
Please **circle a number** on each scale in response to the question

0 = Not confident 10= Extremely Confident

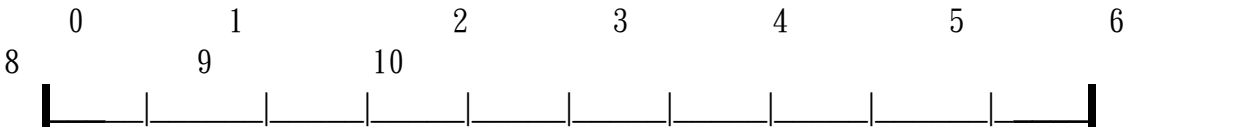
1. I am **comfortable telling others** that I suffer from Chronic Kidney Disease (CKD)



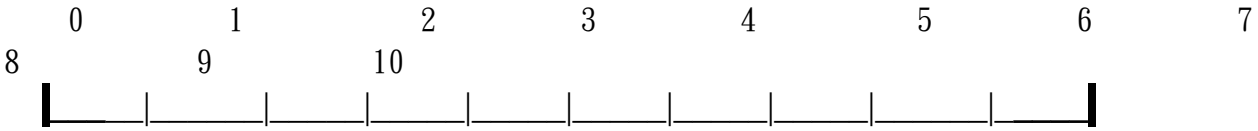
2. I can actively **seek out information** that explains the CKD related signs and symptoms (like high blood pressure, protein in my urine, and fluid retention etc).



3. I can **understand the meaning** of the CKD-related blood and urine results.



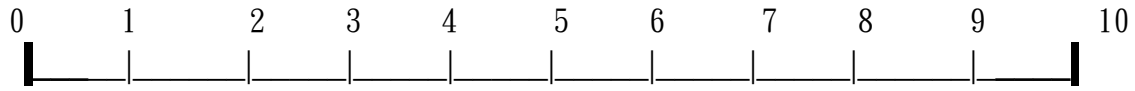
4. I can **accept the fact** that I suffer from chronic kidney disease.



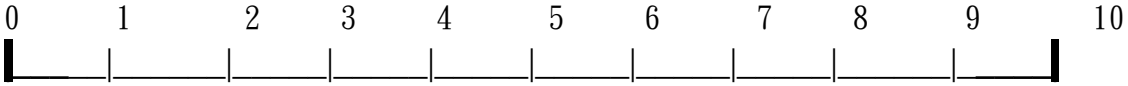
Please **circle a number** on each scale in response to the question

0 = Not confident **10= Extremely Confident**

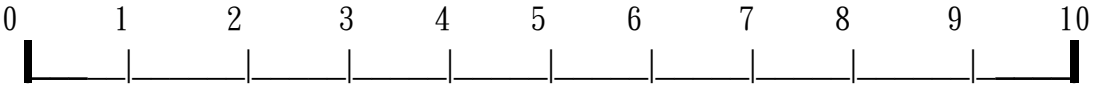
5. I **understand the risk factors** associated with CKD, like high blood pressure, diabetes, drugs etc.



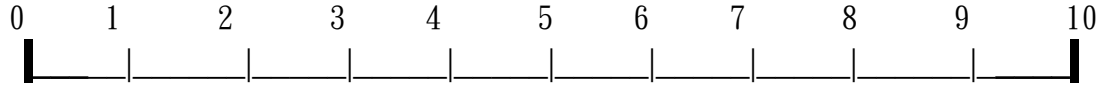
6. I would be able to **discuss my worries** with my family or friends for solutions.



7. I would **seek help** whenever I am stressed out by work or family matters so that it would not affect my disease.



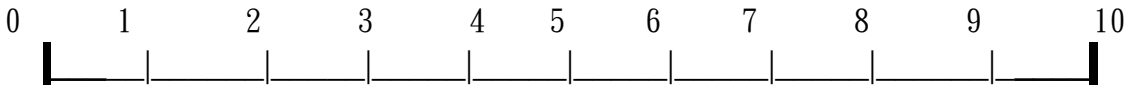
8. I would **actively seek out necessary precautions** to prevent my CKD from worsening.



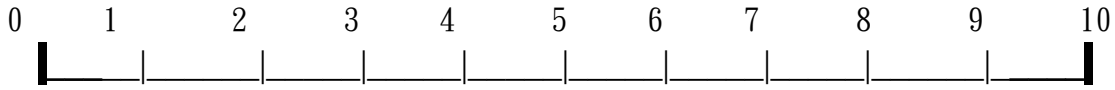
Please **circle a number** on each scale in response to the question

0 = Not confident **10= Extremely Confident**

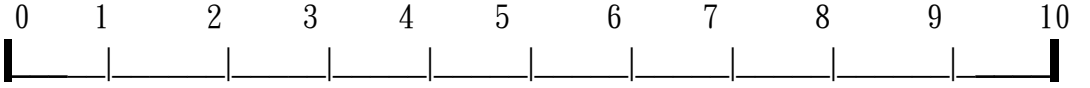
9. I am **willing to share my experience** of self-managing CKD with other patients.



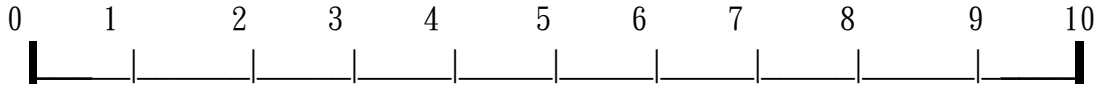
10. I would be **able to adjust my management** (e.g. food consumption, amount of activity, and medication etc.) of my CKD to fit different situations (like travelling or during festivities or celebrations etc.).



11. I am **comfortable asking health care professionals** about my current medical conditions



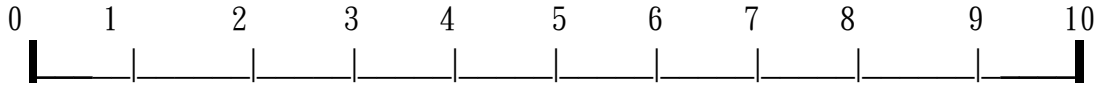
12. I can **face the challenges** of living with CKD



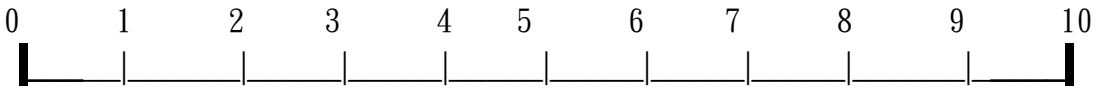
Please **circle a number** on each scale in response to the question

0 = Not confident **10=Extremely Confident**

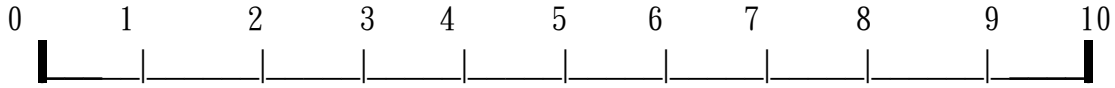
13. I can actively **seek out resources** for better control of my CKD
e.g. advice on eating habits; guidance on diabetes control; information on the medication you use



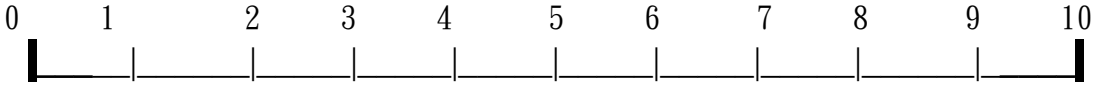
14. I can **actively tell my family and/or friends** about my CKD treatment plans (like diet control and medication etc.) to gain their support.



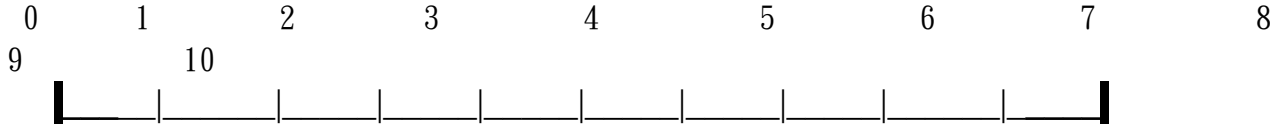
15. I would be **able to control my diet**, even if I am attending a wedding or celebration, in order not to increase the workload on my kidney.



16. I would be **able to manage my CKD** as I am maintaining my health.



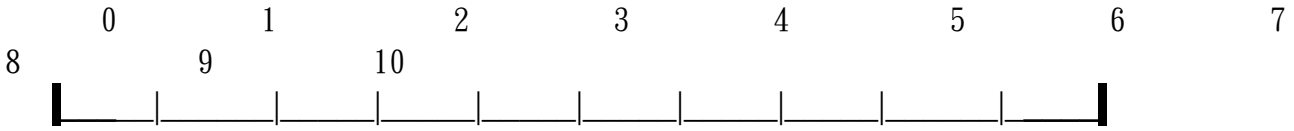
17. I would take the **initiative to tell any doctors** looking after me that I am suffering from CKD.



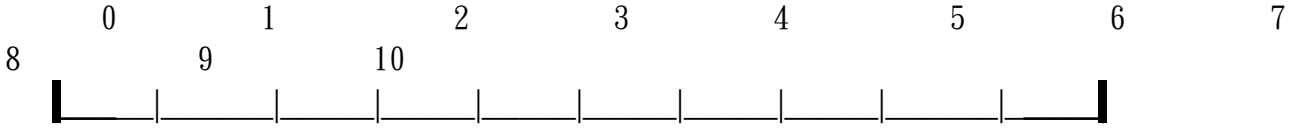
Please **circle a number** on each scale in response to the question

0 = Not confident **10=Extremely Confident**

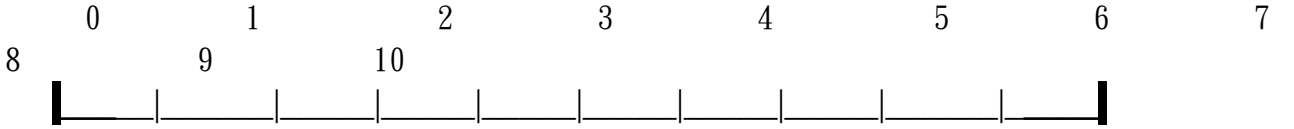
18. I would take the **initiative to ask my doctor for advice** whenever any questions about my medications occur to me.



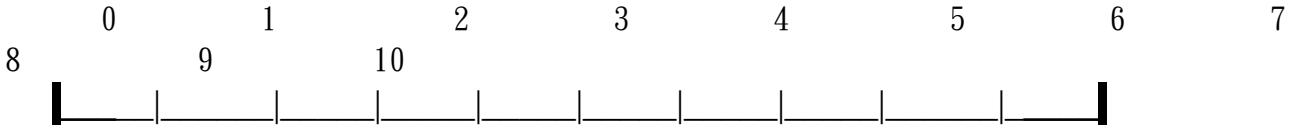
19. I would be **able to choose** the type and amount of food appropriate to my disease when participating in social activities.



20. I would be able to **look for information related** to CKD through various channels (e.g. Internet, flyers, magazines, newspapers).



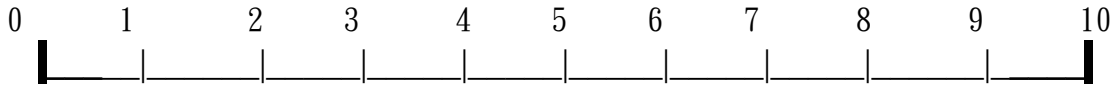
21. I would take the **initiative to contact** the healthcare professionals looking after me for advice whenever any questions about my disease or treatment occur to me, even without a scheduled appointment.



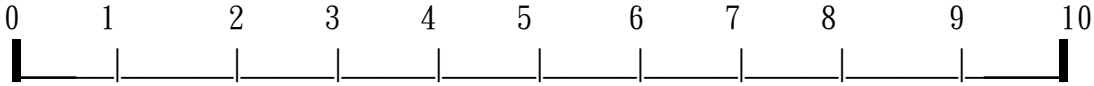
Please **circle a number** on each scale in response to the question

0 = Not confident **10=Extremely Confident**

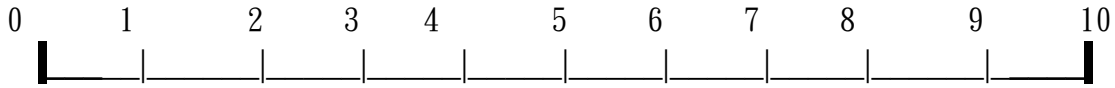
22. I would be **able to adhere to the diet** restrictions recommended by the healthcare professionals.



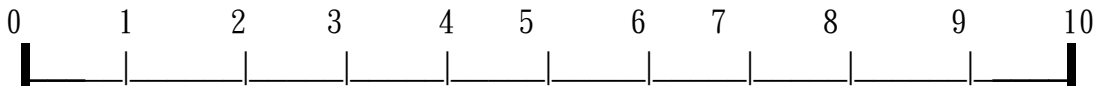
23. I would be **able to adjust my dietary habits** in accordance with the recommendations of the dietitians or health care professionals.



24. I would **selectively participate in social activities** (e.g. attending dinners or gatherings) in order to control of my CKD.



25. I can actively **seek help from my family or friends** whenever I am feeling depressed or frustrated with my CKD



Thank you for taking the time to complete this questionnaire.

Appendix 13 Participant questionnaire: KiKS

Countess of Chester Hospital NHS
NHS Foundation Trust

Kidney Disease Knowledge Survey

Please tick the box next to the answer you think is correct

1. On average, your blood pressure should be:

- ☐ 160/90
- ☐ 150/100
- ☐ 170/80
- ☐ Lower than 130/80

2. Are there certain medications your doctor can prescribe to help keep your kidneys as healthy as possible?

Yes ☐ No ☐

3. Why is too much protein in the urine not good for the kidney?

- ☐ It can scar the kidney
- ☐ It is a sign of kidney damage
- ☐ It is a sign of kidney damage and can scar the kidney
- ☐ It can cause an infection in the urine
- ☐ All of the above

4. What does GFR stand for?

- ☐ Glomerular Filtration Rate- tells us level of kidney function
- ☐ Good Flow Renal- tells us about flow of urine from kidneys
- ☐ Gain for Real- tells us if your kidney function is improving
- ☐ Glucose Function Rate- tells us about your blood sugar level

5. Are there stages of CHRONIC kidney disease?

Yes ☐ No ☐

6. Does Chronic Kidney Disease increase a person's chances of a heart attack?

Yes ☐ No ☐

7. Does Chronic Kidney Disease increase a person's chance for death from any cause?

Yes ☐ No ☐

8. This section is about WHAT THE KIDNEY DOES.

Please select one answer to each question below.

	Yes	**No**
Does the kidney make urine?	☐	☐
Does the kidney clean blood?	☐	☐
Does the kidney help keep bones healthy?	☐	☐
Does the kidney keep a person from losing their hair?	☐	☐
Does the kidney help keep red blood cell count normal?	☐	☐
Does the kidney help keep blood pressure normal?	☐	☐
Does the kidney help keep blood sugar normal?	☐	☐
Does the kidney keep potassium levels in the blood normal?	☐	☐
Does the kidney keep phosphorus levels normal?	☐	☐

Appendix 14 Qualitative interview schedule

Countess of Chester Hospital NHS
NHS Foundation Trust

University of Chester

Qualitative Interview Schedule for structured interviews (Contact 3)

1) Please can you tell me about your overall opinion of the education session?
2) In your opinion, what are the key messages you took from the session?
3) Please can you tell me in what ways the session helped you?
4) Could you please tell me about any changes in your lifestyle you have made since attending the course?
5) Are there any other changes that you intend to make or would like to make?
6) What do you see as the benefits to making the lifestyle changes suggested?
7) Are there any disbenefits to making the lifestyle changes?
8) Can you tell me what has helped you in making lifestyle changes?
9) Can you tell me what has hindered you in making lifestyle changes?
10) In your opinion, is there any further advice or support that would be helpful to you at this stage?

Appendix 15 Research Bursary: Cheshire & Wirral Partnership NHS Foundation Trust

Dear Susan,

I'm pleased to say that your research bursary has been approved, and can be invoiced for in April, from CWP.

I hope all is progressing well, and please let me know if you have any queries.

Best wishes, Phil

Dr Phil Elliott
Senior Research Facilitator
Cheshire and Wirral Partnership NHS Foundation Trust
and NHS Western Cheshire
1829 Building
Countess of Chester Health Park
Liverpool Road
CHESTER
CH2 1HJ

From: Gallagher Susan (COUNTESS OF CHESTER HOSPITAL NHS FOUNDATION TRUST)
Sent: 11 March 2013 15:18
To: Phil Elliott
Subject: Bursary Application: A modular approach to diabetes structured group education

Dear Dr. Elliot
Please find attached an application for a bursary to develop and carry out research within Cheshire, Warrington and Wirral.
In brief, the project is entitled "A modular approach to diabetes structured group education: The effects of Diabetes Essentials: Kidneys on patient knowledge, self-efficacy, self-care behaviour and patient experience in diabetic kidney disease".
The project aims to determine the effects of structured group education for patients and will be carried out at the Diabetes Unit at the Countess of Chester NHS Foundation Trust. It will involve patients from Western Cheshire Clinical Commissioning Group. The project has received approval from NHS National Research Ethics Committee and the Countess of Chester NHS Foundation Trust.
Should you have any questions, please contact me by email or on
Yours sincerely
Susan
Susan Gallagher
Dietitian

Countess of Chester Hospital NHS Foundation Trust
Countess of Chester Health Park
Liverpool Road
Chester
Cheshire
CH2 1UL
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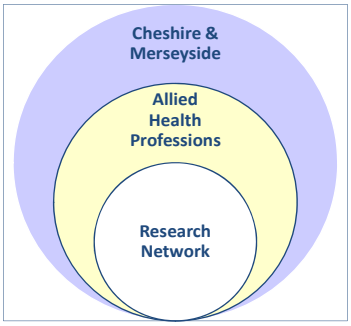
Appendix 16 A Research Bursary: Cheshire and Merseyside Allied Healthcare Professional Application showing travel expenses reimbursement

Cheshire and Merseyside Allied Health Professions (AHP) Research Network **Research Bursary Application Form**	

TOTAL COSTS REQUESTED (Must not exceed £1000 – direct costs)
Transcription cost for twelve structured interviews: £490 Payment of public expenses: £489.60 **Total Requested:** £979.60
COST JUSTIFICATION (500 words)
The transcription cost for twelve structured interviews amounts to £490. Qualitative research will be employed in order to gain understanding about the patient experience of education and its impact on their self-care practices, whilst also aiding understanding of the relationship between the reported quantitative outcome measures. This will assist in assessing the multi-factorial approach required for the management of this chronic disease. The qualitative interviews will be entirely voice recorded. The cost associated with transcribing the audio recording is £490. **Cost of travel**: All reasonable cost of travel will be reimbursed to research participants. This will be provided at a rate of £0.40/mile. Planning for travel from the boundaries of Western Cheshire Clinical Commission Group boundaries to the study venue is approximately 17 miles, each way. A return journey would cost £13.60 and with participants expected to attend three visits over the duration of the study this would result in a cost of £40.80/participant. Minimum recruitment is anticipated as twelve people. Therefore travel expenses (12 participants with 3 journeys at £13.60/visit) are estimated as £489.60.

Appendix 16 B Research Bursary: Cheshire and Merseyside Allied Healthcare Professional Invoice

Appendix 17 Research Bursary: Lily Grants & Donations

10th May 2013
Susan Gallagher
Diabetes Research Dietitian
Countess of Chester Hospital NHS Foundation Trust
Liverpool Road
Chester
CH2 1UL

Dear Susan,

Re: Grant/Donation Application
I am pleased to inform you that the Lilly Grants and Donations Committee have approved a grant to Countess of Chester Hospital NHS Foundation Trust for the sum of £4,000 towards your project looking at a modular approach to diabetes structured group education. Please provide full bank details of Chester Hospital on headed paper so a bank transfer can be arranged.
If the entire grant/donation sum is not used, please contact me to arrange for the return of these unused funds to Lilly UK. If you have any questions, please call the Lilly UK switchboard on 01256 315000 and ask to speak to the Grants and Donations Committee Secretary.

Lilly's decision to grant you funding is not intended to, and should not, influence the decision of any person or institution to purchase and/or prescribe Lilly medicines or otherwise influence any future or pending business with Lilly. We require that Countess of Chester Hospital NHS Foundation Trust comply with all applicable UK & US anti-bribery laws. Lilly hereby confirms that our decision to grant you funding has been made on the understanding that Countess of Chester Hospital NHS Foundation Trust will not give or promise to give, and will not make, offer, agree to make or authorize any payment or transfer anything of value, directly or indirectly, (i) to any Government or Public Official; (ii) any political party, party official or candidate for public or political office; (iii) any person while knowing or having reason to know that all or a portion of the value will be offered, given, or promised, directly or indirectly, to anyone described in items (i) or (ii) above; or (iv) any owner, director, employee, representative or agent of any actual or potential customer of Lilly in consequence of it. Additionally, we require that Countess of Chester Hospital NHS Foundation Trust take no action that might cause Lilly to be in violation of any applicable UK & US anti-bribery laws.

If any of the above is unacceptable to you, then, please contact the Secretary of the Lilly Grants and Donations Committee on or at the address at the head of this letter and we shall withdraw the grant offer.

Yours sincerely,
Grants and Donations Committee

Lilly UK
Lilly House, Priestley Road
Basingstoke, Hampshire, RG24 9NL
UNITED KINGDOM
Tel: +44 (0)1256 775042 Fax: +44 (0)1256 775858
www.lilly.co.uk

Appendix 18 Research Funding: Countess of Chester NHS Foundation Trust Diabetes Research Unit

Countess of Chester Hospital NHS
NHS Foundation Trust

The Countess of Chester Health Park
Liverpool Road
Chester CH2 1UL

Direct Dial: 01244 363745
e-mail: frank.joseph@nhs.net

Project Title: A modular approach to Diabetes structured group education: The effects of Diabetes Essentials: Kidneys on patient knowledge, self-efficacy, self-care behaviour and patient experience.

The funding of this research project will be provided by the Countess of Chester Hospital NHS Foundation Trust Diabetes Research Fund.
This funding covers all cost associated with the research which includes the following:

- Employment of the principal investigator (Diabetes Research Dietitian)
- Resources required for the printing and postage of the required patient information material and questionnaires
- Travel expenses for research participants
- Funding the external involvement for the qualitative element of the research provided by the Centre for Public Health at Liverpool John Moores University

Dr Frank Joseph
Consultant Physician in Endocrinology & Diabetes

Appendix 19 “Diabetes Essentials: Kidneys” module information

‘Diabetes Essential’ is a package of structured diabetes group education provided by the Countess of Chester Hospital NHS Foundation Trust and commissioned by the Western Cheshire Clinical Commission Group. This education package is a tiered approach to the provision of education, grounded by the basic education (Diabetes Essentials), and building on this with more intensive specialist education for the complication of diabetes e.g. Diabetes Essentials: Kidneys; Diabetes Essentials: Foot and it also facilitates the specialist needs of specific sub-populations e.g. Gestational diabetes (Diabetes Essentials: GDM) and carbohydrate counting and insulin dose adjustment (Diet and Insulin dose adjustment at the Countess, [DISC]).

‘Diabetes Essentials: Kidneys’ is a complication specific module targeting patients with DKD, delivered as a two hour group session at the diabetes specialist unit of the Countess of Chester Hospital NHS Foundation Trust. It aims to provide patients with the knowledge, skills and confidence to advance their management practices in view of their condition.

Topics to be delivered in this education course are based on NICE guidelines (NICE, 2004; NICE, 2008; NICE, 2008) and nationally recognised evidenced based nutritional guidelines for the management of diabetes (Dyson, et. al., 2011) and incorporation of aspects of clinical care identified as appropriate and necessary by the multi-disciplinary team with interest in DKD.

The multi-disciplinary team comprised of Consultants in Endocrinology and Diabetology, a DSN with special interest in DKD, a renal specialist nurse and diabetes and renal specialist dietitans. This multi-disciplinary approach help ensured all relevant recommendations and information were included. The views and opinions of lay persons

with diabetes were also considered through consultation with the local Diabetes UK voluntary group. The emphasis is on empowering patients by explaining medical terminology, interpreting test results and encouraging participation in self-care, thereby promoting a shared care approach to the condition. Advice on anti-hypertensive medication, diet and lifestyle are combined with this in order to enable patients to self-manage their condition and to re-enforce advice they may have had previously.

The learning outcomes of the session agreed were to:

- Promote awareness of what kidneys do
- Increase understand of how diabetes affects your kidneys
- Increase ability to interpret urine and blood tests results specific to the condition
- Improve understand of the effects of kidney disease
- Understand the importance of good blood pressure control
- Highlight the importance of medication coherence
- Increase knowledge on the effects of diet and lifestyle on kidney health

The session was deliver in consideration of adult learning principles (Knowles 1984), using a mixture of teaching styles which were identified as preferential learning styles by the local Diabetes UK voluntary group. This involved the use of physical visual aids combined with animations to describe kidney function; food models and food label to encouraged discussion, learning and practical skills with regards to food choices; and quizzes to emphasis important element with regards to the benefits of management and medication usage.